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(54) **Title:** A METHOD FOR ENABLING A USER TO DETECT A STATUS OF A MEDICAMENT DELIVERY DEVICE

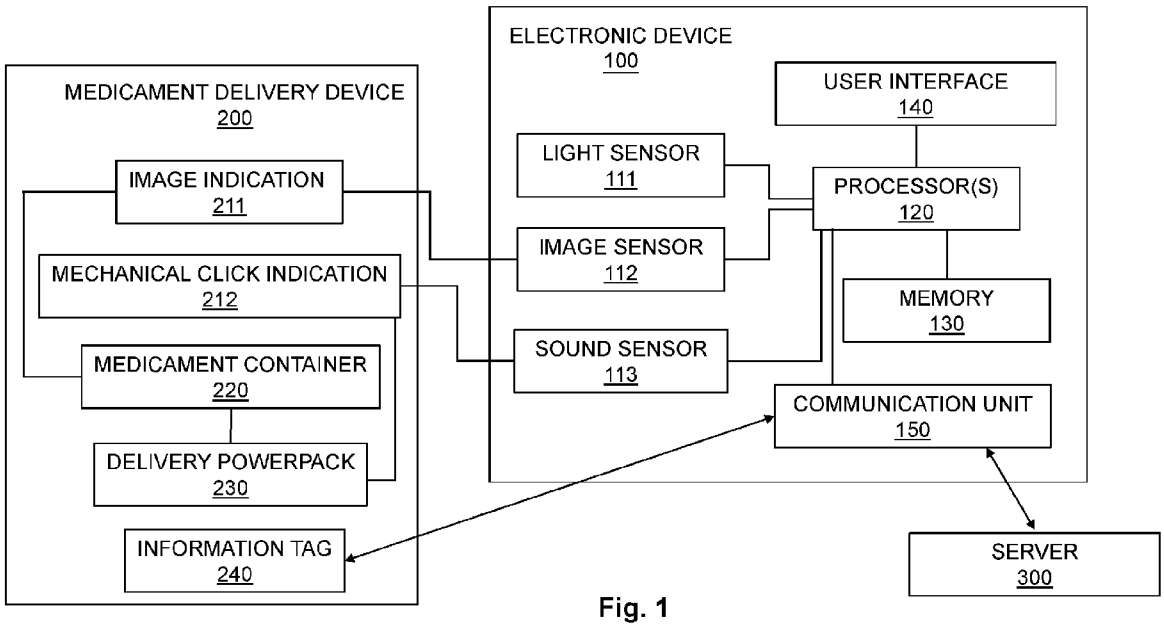

Fig. 1

(57) **Abstract:** A method for enabling a user to detect a status of a medicament delivery device The present disclosure provides a method for enabling a user to detect a status of a medicament delivery device (200) The method includes capturing at least one of a light signal, an image signal and an audible signal generated by the medicament delivery device via at least one of a light sensor (111), an image sensor (112) and a sound sensor (113) of an electronic device (100). The method further includes fetching information from a database with the captured signal. The method further includes providing an indication based on the fetched information to a user of the medicament delivery device (200) via a user interface (140) of the electronic device (100).

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TITLE

A method for enabling a user to detect a status of a medicament delivery device

TECHNICAL FIELD

The present disclosure provides apparatuses and methods enabling a user to detect a status of a medicament delivery device, in particular, a method comprising a step of capturing at least one of a light signal, an image signal, and an audible signal generated by the medicament delivery device via at least one of a light sensor, an image sensor, and a sound sensor of an electronic device to detect a status of a medicament delivery device.

BACKGROUND

Unless otherwise indicated herein, the materials described in this section are not prior art to the claims in this application and are not admitted to be prior art by inclusion in this section.

Many medicament delivery devices such as auto-injectors are generally known for the self-administration of medicament by patients without formal medical training. Most of the self-administration medicament delivery devices are arranged with indication functions to guide the patients to use the medicament delivery device correctly. However, to avoid the higher cost of the medicament delivery devices, medicament delivery devices do not usually have complex processor units. Some disposable medicament delivery devices might not have any electronics. As a result, the indication provided by medicament delivery devices are usually simple, e.g., color codes, click sounds, simple icons, or a combination thereof. Those simple indications might be difficult for the patients to interpret.

In particular, when patients need to receive different treatments from different medicament delivery devices or the patients are prescribed with different medicament delivery devices for the same treatment, long and/or frequent training might be needed for the patients; otherwise, the operation errors of the medicament

delivery devices might increase as the patients might not correctly interpret the indication provided by the medicament delivery devices.

Further, some large volume medicament delivery devices utilize a disposable or pre-filled syringe as a primary drug container. In these designs, the syringe is loaded into a pre-determined position, such as a carrier, slot, or bracket.

These pump designs use combinations of syringe geometry and features to locate and/or retain them within the medicament delivery device. Syringe geometry can include size-specific aspects, such as those differing between 10, 20, 30, or 50/60mL designs. Syringe features can include size-specific aspects such as flange size, thickness, shape, barrel outer diameter, or contour of the distal syringe cone and luer connection. Once positioned and retained, a drive mechanism (e.g., a flat, clock, or coil spring) applies force to the syringe to dispense medication.

As with any medicament delivery device, feedback on an injection, such as start of dose (SOD), end of dose (EOD), and in process feedback (IPF) are important indicators that are often required for regulatory approval of medicament delivery devices.

In some cases, the user of the device can manually view and interpret progress by viewing a moving stopper through the device window. For instance, in some prior art devices, users may view relative stopper position and movement through a device window to estimate injection process.

Notably, in some prior art embodiments the scale marking is visible during drug delivery, but this need not be the case. For instance, a user may load the syringe rotated 180°, in which case, the stopper would be visible, while the syringe markings would not be visible through the window. In this instance, only relative measurement of progress could be estimated by a user. Thus, improved approaches are needed to provide users with a more accurate estimation of progress and time remaining.

Moreover, in the case of large volume devices, flow rates can be low. For instance, in a 30mL injection at 1mL/min, movement of the stopper would be one minor syringe marking line per minute. Put another way, a user would have to maintain sight of the syringe for a full minute to verify medication administration, which is impractical. Similarly, shorter glances may not be practical to readily compare movement from a prior position.

This is relevant because infusion times for longer volumes may be considerable. In the instance above, the infusion would be nominally 30 minutes long. In these cases, responsibility is on the user to identify discrepancies and address them if applicable. For instance, a user checking device progress intermittently might not readily identify a stalled infusion. Thus, improved approaches are needed to provide users with information about medication administration progress for longer infusions.

Complicating this further, injection progress (e.g., the rate of injection) can be highly variable. This is especially the case for biologics, which are viscous and have strong temperature sensitivity, which affects overall injection time and rate, especially in systems that use hydraulic resistance to throttle flow.

Additionally, even in the case of room-temperature injection and Newtonian fluids, some delivery systems may have variable rates throughout the injection, despite a single average flow rate over the entire infusion. This implies movement between scale markings may be different at different points in the infusion, which is potentially confusing to a user of the device. Thus, improved approaches are needed to provide specific feedback on progress of an infusion, taking into account the underlying characteristics of the delivery device, and present these to the user in an easily understandable way during the course of delivery.

SUMMARY

The invention is defined by the appended claims, to which reference should now be made.

There is hence provided a method for enabling a user to detect a status of a medicament delivery device, the method comprising the following steps in the following order:

capturing at least one of a light signal, an image signal and an audible signal generated by the medicament delivery device via at least one of a light sensor, an image sensor and a sound sensor of an electronic device;

fetching information from a database with the captured signal; and

providing an indication based on the fetched information to a user of the medicament delivery device via a user interface of the electronic device.

The method is configured to capture the indications provided by the medicament delivery device and interpret the captured indications for the user. In the case that a user needs to receive different treatments from different medicament delivery devices and/or the user is prescribed another medicament delivery device for the same treatment, the user doesn't need to remember the meaning of all indications provided by different medicament delivery devices and the operation errors of the medicament delivery devices due to the misunderstanding of the meaning of the indication generated by the medicament delivery device can be reduced.

Preferably, according to another embodiment, the method comprises a step of selecting a type of indication to be provided to the user based on inputted user information.

In this example, the indication provided by the method can be tailored-made to different patients, e.g., elders, children, patients with vision impairment, patients with color blindness, and/or patients with hearing impairment. This customized indication can be done by simply programming the software or selecting from pre-programmed models instead of re-designs the medicament delivery devices. For example, patients who receive the same treatment usually are prescribed the same medication delivery

device. Within the same patient group, some patients might have vision impairment and some patients might have a hearing impairment. However, the same type of medicament delivery devices usually only has one set of indications, e.g., a combination of sounds and vision, and the sound indication might be loud enough for most patients but not loud enough for some other patients for example. The method provides an easy way to customize the indication for different patients and thus can mitigate the potential operation errors of the self-administration medicament delivery devices.

Preferably, according to another embodiment, the indication provided to the user is presented to the user with at least one of text message, voice message, animation, and a vibration indication.

Preferably, according to another embodiment, the method is configured to be operated by a processor of an electronic device; wherein the electronic device comprises a memory coupled to the processor, at least one of a light sensor, an image sensor and a sound sensor, and a user interface.

Preferably, according to another embodiment, the electronic device is a mobile device, e.g., mobile phones, tablet computers, smart watches, and/or smart speaker.

In this example, as the method is operated by the electronic device, preferably, a mobile device, a more complex indication can be provided. For example, the sound sensor can capture an end click of a medicament delivery device and the image sensor can capture an image that a plunger rod of the medicament delivery device is positioned within a medicament container. The sound signal and the image signal can be interpreted as the status of the medicament delivery device that the medicament delivery operation is completed. Thus, the indication provided by the method can be a human voice in a local language via a speaker of the mobile phone to the user.

Preferably, according to another embodiment, the step of capturing at least one of a light signal, an image signal and an audible signal of the medicament delivery device

comprises a step of capturing at least one of a subvisible light signal and a subaudible sound signal generated by the medicament delivery device.

Preferably, according to another embodiment, the at least one of the subvisible light signal and the subaudible sound signal is configured to contain encoded information related to the medicament delivery device.

In this example, the visible light and/or image signal and/or the audible signal generated from the medicament delivery device can be used to serve its core functionality for medicament delivery device delivery, namely that people can observe the indications generated from the medicament delivery device to understand the status the medicament delivery device and provide help to the patient who is needed. The at least one of a subvisible light signal and a subaudible sound signal can be used to carry more detailed information such as the information related to the dosage delivered, the ordinal number of a medication sequence, or the number of medicament containers administered in a dosing interval.

Preferably, according to another embodiment, after the step of providing an indication based on the fetched information to a user of the medicament delivery device, the method further comprises the following steps in the following order: repeating all operated steps in the same operated order.

As most of the medicament delivery devices comprise continuous indication, e.g., the plunger rod will continue to move within the medicament container until the end of the medicament delivery operation, repeating the steps mentioned above results in providing the patients with real-time information about the medicament delivery device. For example, the patients can be indicated with the remaining medicament delivery time or delivery progress as what percentage has been completed in a more understandable way (as the indication can be customized for the patients or is closer to the human language).

The captured signal can also be video, e.g., captured by repeating the step of capturing images signal.

Preferably, according to another embodiment, the indication provided to the user comprises content related to the medicament delivery device. The content comprises at least one of instructional content, warning content, troubleshooting content, and informational content.

The instructional content can be used to instruct the patients about the operation steps that the patients need to perform in order to properly complete the medicament delivery operation. The warning content can be used to warn the patients to avoid any action that might harm the patients, e.g., injury or incorrect dosage. The troubleshooting content can be used to guide the patients to solve an issue of the medicament delivery device. For example, in one example where the medicament delivery device is a motor-driven device and comprises electronics, if an error code related to a specific error is captured, the troubleshooting content may be more intuitive for a patient since a complex user manual or an instruction for use (IFU) is not required. The troubleshooting content could provide animations or step-by-step instructions to resolve the specific error. This is particularly useful when the manual or IFU is not available, or when users are easily overwhelmed by instructions or have low health literacy. The informational content can be used to indicate to the user the current status of the medicament delivery device and/or any potential next status of the medicament delivery device.

Preferably, according to another embodiment, the step of fetching information from a database with the captured signal comprises the following steps in the following order: searching for information from the database stored in a memory of the electronic device; matching the information with the captured signal; and retrieving the matched information.

In this example, the database is stored in the electronic device. Thus, an internet connection is not necessary.

Alternatively or additionally, according to another embodiment, the step of fetching information from a database with the captured signal comprises the following steps in the following order: searching information from the database stored in the memory of the electronic device; matching the information with the captured signal; and retrieving the matched information.

In this example, the patients can always get the latest information about the medicament delivery device.

Preferably, according to another embodiment, before the step of capturing at least one of a light signal, an image signal and an audible signal of the medicament delivery device, the method comprises a step of receiving an activation signal from an action of a user on the user interface or a wirelessly transmitted activation signal.

Thus, the patients can start the steps of the method by for example opening an application on the mobile phone and scanning QR code or NFC on the device.

Preferably, according to another embodiment, the method as mentioned above is a method of operating a computer system.

Preferably, according to another embodiment, the computer system comprises memory storing instructions and one or more processors coupled to the memory to execute the instructions, wherein the instructions, when executed by the one or more processors, cause the system to implement the method as mentioned above.

Preferably, according to another embodiment, companion software comprising instructions to carry out the method is provided.

Preferably, according to another embodiment, the software is an application configured to be executed on a mobile device and when the software is executed on a

mobile device by the processor of the mobile device, the processor causes the method disclosed herein to be implement by the mobile device.

Another aspect of the invention provides a system for guiding a user of a medicament delivery device to use the medicament delivery device, the system comprising an electronic device, the electronic device comprising: a processor configured to operate the method as mentioned in any embodiment above, a memory coupled to the processor; at least one of a light sensor, an image sensor and a sound sensor, and a user interface.

Preferably, according to another embodiment, the database is stored in the memory of the electronic device.

Alternatively or additionally, according to another embodiment, the database is in a remote server; and wherein the processor is configured to establish a communication with the remote server before operating the method according to any one of the above-mentioned embodiment.

Further principlese and embodiments of the present disclosure relate to improved apparatus and methods to identify, predict, and communicate drug delivery progress utilizing a physical delivery device in concert with software-based computer vision. In one embodiment of the present disclosure, a user utilizes receives pre-processed medicament delivery device administration progress feedback by way of a smartphone camera and software, without a connected medicament delivery device. In another embodiment, the present disclosure further provides calibrating features on medicament delivery device that are positioned relative to a syringe loaded into fixed, predictable position relative to those features. In another embodiment, the present disclosure further provides calibrating visual features are fixed reference points on the device window that are machine-readable, and optionally human readable (if software component unused/unavailable). In another embodiment, the present disclosure further provides using machine vision to identify the syringe

stopper position within a medicament delivery device and interpret medication administration progress. In one embodiment, the present disclosure provides an approach that relies only on underlying syringe geometry and movement of stopper within the syringe and does not rely on the printed or labeled syringe scale, making it insensitive to manufacturing limitations or variability (i.e., this ID is not machine vision reading of a pre-printed scale). In one embodiment, the present disclosure provides progress reported by software incorporates time-based variations in drug delivery rate, effectively compensating for variations in estimates provided to a user.

Furthermore, all terms used in the claims are to be interpreted according to their ordinary meaning in the technical field, unless explicitly defined otherwise herein. All references to "a/an/the element, apparatus, component, means, etc." are to be interpreted openly as referring to at least one instance of the element, apparatus, component, means, etc., unless explicitly stated otherwise.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the inventive concept will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figures 1-2 show simplified block diagrams of an electronic device configured to operate a method of the invention being used with different medicament delivery devices.

Figures 3-4 show the electronic device of Figures 1-2 being used with different medicament delivery devices.

Figure 5 shows a block diagram of the method of the invention.

Figure 6 illustrates a system for detecting a status of a medicament delivery device, according to an example embodiment.

Figure 7 illustrates a syringe installed in the representative medicament delivery device, according to an example embodiment.

Figure 8 illustrates an illustrative example of a complete delivery profile for a representative device, according to an example embodiment.

Figures 9A-9C illustrates an example elastomeric pump, according to an example embodiment.

DETAILED DESCRIPTION

Apparatuses and methods for enabling a user to detect a status of a medicament delivery device is provided. The method is configured to assist users of the medicament delivery device to understand signals generated by the medicament delivery device. The method can be used to assist the user to use a pure mechanical medicament delivery device, e.g., a syringe, an insulin pen, or a disposable auto-injector. Alternatively, the method can be used to assist the user to use a medicament delivery device comprises electronics, e.g., an infusion pump or a reusable motor-driven injection device. The user of the medicament delivery device can be a patient who will receive the medicament contained within the medicament delivery device or people who help the patient to receive the medicament contained within the medicament delivery device, e.g., caregivers.

In a preferred example, the method is configured to be used with an electronic device comprising at least one of a light sensor, an image sensor and a sound sensor; and a user interface. In one example, the user interface is an integral part of the electronic device. Alternatively, or additionally, the at least one of a light sensor, an image sensor and a sound sensor and the user interface can be an independent device that is electrically connected to the electronic device. For example, a user may connect a mobile phone to a smart TV via a cable or wirelessly, e.g., via Bluetooth connection, for example. In this example, the mobile phone can be the electronic device; and the smart TV can be the user interface.

In a preferred example, the electronic device comprises one or more processors. In this example, the method is configured to be operated by the one or more processors of the electronic device. In a preferred example, companion software comprising instructions to carry out the method is provided. In a preferred example, the software is an application configured to be executed on a mobile device, e.g., a mobile phone, a tablet computer, a smart wearable device such as smart watches or smart rings, or a smart speaker. When the software is executed on a mobile device by the processor of the mobile device, the processor causes the method disclosed herein to be implement by the mobile device. In a preferred example, the medicament delivery device is configured to be used around the electronic device.

The method 400 comprises the following steps in the following order, as shown in Figure 5:

- capturing at least one of a light signal, an image signal and an audible signal generated by the medicament delivery device via at least one of a light sensor, an image sensor and a sound sensor of an electronic device (step 401);
- fetching information from a database with the captured signal (step 402); and
- providing an indication based on the fetched information to a user of the medicament delivery device via a user interface of the electronic device (step 403).

Thus, an indication generated by the medicament delivery device can be captured, interpreted, and provided to the user of the medicament delivery device.

In one example as shown in Figure 1, the method 400 is configured to be operated by a processor 120 of an electronic device 100. In this example, the medicament delivery device 200 is a pure mechanical medicament delivery device, in other words, the medicament delivery device does not comprise electronics, such as a

disposable autoinjector. The medicament delivery device 200 comprises a medicament container 220 containing medicament for being delivered to a user of the medicament delivery device 200. The medicament delivery device 200 further comprises a delivery powerpack 230 configured to, upon the medicament delivery device being activated, output force on the contained medicament and thereby cause the contained medicament to be expelled from the medicament container 220. For example, the powerpack 230 comprises a plunger rod connected to a power source. The power source can be a spring or a gas canister. In this example, the delivery powerpack 230 is configured to provide a mechanical click indication. For example, when the plunger rod hits a stopper of the medicament container 220, the user of the medicament delivery device can get an audible signal that indicates the start of the medicament delivery operation. The medicament container 220 can provide an image indication to the user of the medicament delivery device. For example, the user can see the plunger rod positioned within the medicament container 220 after medicament delivery operation or the user can see the decrease of the contained medicament.

In one example where the method 400 is operated by a processor of a mobile phone, the user can use a camera from the mobile phone to be the image sensor to take photos/video of the medicament delivery device 200, as shown in Figure 4. In this example, the processor 120 of the mobile phone is configured to operate the method to capture the image signal generated by the medicament container 220 of the medicament delivery device 200 and the audible signal generated by the delivery powerpack 230 of the medicament delivery device 200 via the camera 112 and the microphone 113. Once the signals are captured, the processor 120 is configured to fetch information from a database with the capture signal. For example, when the captured signal is a click sound generated when the plunger rod hits the stopper of the medicament container, the information that can be fetched with the captured audible signal can be the information of the start of the medicament delivery operation. Once the information is fetched, the processor 120 is configured to

provide an indication of the fetched information to a user of the medicament delivery device via a user interface of the mobile device.

In a preferred example, the indication that is provided to the user is presented to the user with at least one of text message, voice message, animation, and a vibration indication. For example, the indication may be presented with additional words, graphics, animation, sound, or notifications, all of which are not present on the medicament delivery device itself. Moreover, the indication can be presented in a local language. As a result, the user can easily understand the current status of the medicament delivery device via the indication from the mobile device rather than interpreting the different mechanical click sounds from the medicament delivery device. For example, the processor 120 can cause the speaker of the mobile device 100 to output an audible indication in human language and human voice. For example, the user might hear 'Injection starts' from the speaker of the mobile phone.

In one example, the step of fetching information from a database with the captured signal comprises the following steps in the following order:

- searching information from the database stored in a memory of the electronic device;
- matching the information with the captured signal; and
- retrieving the matched information.

In this example, the database is stored in the memory 130 of the electronic device 100. Alternatively, or additionally, the database is connected to a server 300, e.g., a cloud server, preferably, the database is stored in the server 300. In this example, the step of fetching information from a database with the captured signal comprises the following steps in the following order:

- sending a request with the captured signal with a communication unit of the electronic device;

- receiving the information from a server connected to the database with the communication unit of the electronic device.

In this example, once the signals are captured, the processor 120 is configured to send a request with the captured signal with the communication unit 150 of the electronic device 100 to the server 300. The server 300 is configured to match the information with the received request, retrieve the matched information, and then send the retrieved information to the electronic device 100. Thus, the mobile device can receive the information from the server via the communication unit 150.

Furthermore, before the step of capturing at least one of a light signal, an image signal and an audible signal of the medicament delivery device, the method comprises a step of: receiving an activation signal from an action of a user on the user interface or a wirelessly transmitted activation signal. In one example where the processor 120 of the electronic device 100 is configured to operate the above-mentioned method, the processor 120 will start to cause the at least one sensor to capture the signal generated by the medicament delivery device only when the processor receives an activation signal from an action of the user. For example, the user can open an application on the mobile device, and/or scan QR code, and/or place the mobile device nearby an RFID/NFC tag on the medicament delivery device. In one example, the medicament delivery device is arranged with an information tag 240, e.g., an RFID/NFC tag. In this example, the communication unit 150 of the mobile device may comprise an RFID/NFC reader to receive a signal when the mobile device is placed nearby the medicament delivery device. Thus, the processor 120 can receive the activation signal from the communication unit 150 to start the operation of the method as mentioned above.

Furthermore, in a preferred example, after the step of providing an indication based on the fetched information to a user of the medicament delivery device, the method further comprises the following steps in the following order: repeating all operated steps in the same operated order. In a preferred example, all operated steps will be

repeated until an operation-completed signal is detected. The operation completed signal can be designed dependent on the design. For example, the operation completed signal can be a signal that the user closes the application of the mobile device, or the user moves the mobile device away from the medicament delivery device (out of the communication range that the RFID/NFC tag can be read by the mobile device), or a detection of the end of the medicament delivery operation by the method mentioned above, or the absence of actions being taken by the at least one of a light sensor, an image sensor and a sound sensor of an electronic device in a period of time, e.g., 5 seconds or 10 seconds. As the method mentioned above will be repeated, preferably, during the entire period of the medicament delivery operation, the user of the medicament delivery device can get real-time information about the status of the medicament delivery operation. For example, the user can get an indication about the progress of the medicament delivery operation, e.g., how many percentages of the medicament is delivered.

In another preferred example, the method comprises a step of selecting a type of indications to be provided to the user based on inputted user information. For example, a caregiver can select a type of indications for individual patients, e.g., for patients with vision impairment, the indications can be selected to be audible indication.

In another example, the medicament delivery device may comprise electronics, e.g., an infusion pump or a reusable motor-driven injection device, as shown in Figure 2. This type of medicament delivery device is commonly used for delivering high volume/high viscosity medicament and/or long period of the medicament delivery, e.g., long hours or couple days. Thus, this type of the medicament delivery device usually is arranged with more complicated indications as there might be more actions that the user needs to carry out and/or there might be more events that the user needs to be aware of.

In one example, the medicament delivery device 200' comprises a light emitter 213', e.g., LED light, an image indicator 211, e.g., icons, a speaker 212', and a processor 250'. As mentioned above, the medicament delivery device 200' also comprises at least one medicament container 220' and a delivery powerpack 230. In one example, the medicament container 220' can be packed in a cassette that is releasably attached to a reusable part of the medicament delivery device 200', as shown in Figure 5. In this example, the electronics and the delivery powerpack 230 are positioned within the reusable part of the medicament delivery device 200'. Alternatively, the medicament container can be preassembled within the medicament delivery device. The medicament delivery device may comprise multiple medicament containers containing with the same or different medicaments. In one example where the medicament delivery device comprises multiple medicament containers containing with different medicaments respectively, the medicaments may be configured to be delivered to the patient in a predetermined sequence. In one example, the delivery powerpack 230 can be a motor or an air pump. In a preferred example, the medicament delivery device 200' comprises a battery 260' and a communication unit 240'.

The steps of the method as mentioned in any of the above examples are all applicable to this example. Thus, those steps will not be repeated in the below example again as they are already explained in detail above.

In one example where the medicament delivery device is provided with icons and LED indicators, the signal captured, interpreted and indicated with the method mentioned above is shown in Table 1 below as an example. In this example, the above-mentioned method is operated by the processor 120 of the mobile device 100.

Table 1

The signal collected by the	Fetched	Indication displayed by the

image sensor		**information**	**mobile device to a user**
Icon(s)	**LED(s)**		**Displayed Content**
Progress Bar	Green	Device delivering medication	Elapsed, remaining injection time[N] Delivery progress as % completed[N] Caution not to move/dislodge the delivery device[W]
Check Mark	Green, flashing	Device is ready for delivery	Steps to start the delivery device[I] What to expect once delivery starts[N]
	Green, static	Delivery complete	Steps to remove the delivery device from skin[I] Steps to safely dispose of the delivery device[I]
"X" Mark	Red, flashing rapidly	Battery charge insufficient (recoverable error)	Charging instructions[T] Time to sufficient charge[T]
Check and "X" Mark	Red	Device malfunction (fatal error)	Incomplete dose delivered, and what to tell prescribing physician[N] Caution to remove the device and return to pharma company[W]

			Link to the pharma company website to submit product complaint and request replacement dose[T]

I = instructional content, W = warning content, T = troubleshooting content, N = informational content

As shown in this example, preferably, the indication that is provided to the user comprises content related to the medicament delivery device. In a preferred example, the content comprises at least one of instructional content, warning content, troubleshooting content, and informational content. The Instructional content helps the user operate the medicament delivery device correctly, e.g., guiding the users to connect multiple cassettes to the medicament delivery device in a specific order, while informational content helps the user understand what is taking place with one or more aspects of the medicament delivery device (or medication delivery operation). Warning content may also be displayed for unsafe or undesired operating conditions and troubleshooting content may be displayed when an error occurs that can be corrected by user action.

In one example, the medicament delivery device 200’ comprises the information regarding the interpretation of the indications that the medicament delivery device 200’ can provide, the user operation manual of the medicament delivery device, and the information related to the medicament. In this example, the communication unit 240' of the medicament delivery device 200' can send the information to the communication unit 150 of the mobile device 100 when the user establishes a communication between the medicament delivery device 200' and the mobile device 100. In this example, the information can be stored in the database stored in the mobile device for being fetched with a specific captured signal of the medicament delivery device during use.

Furthermore, some of medicament delivery devices having electronics can output the indication, e.g., light, sound, or images, carrying encoded information.

Furthermore, some of medicament delivery devices having electronics can provide at least one of a subvisible light signal, e.g., infrared, or small color/luminance change by pulsing LEDs, and a subaudible sound signal, e.g., ultrasound or a barely audible tone.

Thus, in another example, the step of capturing at least one of a light signal, an image signal and an audible signal of the medicament delivery device comprises a step of: capturing at least one of a subvisible light signal and a subaudible sound signal generated by the medicament delivery device.

In a preferred example, the encoded information can be interpreted by the processor 120 of the electronic device 100 when the indications are captured. In one example where the medicament delivery device can provide at least one of the human-invisible and the subaudible sound signal, it may be preferred to have the at least one of the subvisible light signal and the subaudible sound signal to carry the encoded information.

In one example where the medicament delivery device comprises LED indicators and can generate the subvisible light signal, the signal captured, interpretation and indicated with the method mentioned above is shown in Table 2 below. In this example, the above-mentioned method is operated by the processor 120 of the mobile device 100.

Table 2

Data collected by the light sensor	**Fetched information**	**Indication displayed by the mobile device to a user**

Visible LEDs	**Subvisible LEDs**		**Tailored Content (App)**
Green, flashing	Pulsing LEDs encoding remaining delivery time in seconds	Device delivering medication	Elapsed, remaining delivery time[N] Delivery progress as % completed[N] Caution not to move/dislodge device[W]
Orange	Pulsing LEDs encoding delivered dose	Premature delivery device removal	Partial dose delivered[W] Actual volume delivered[N] What to tell prescribing physician[N]
Half LEDs array is green, and the other half of LEDs array is orange		Only one of the two cassettes dispensed	Incomplete regimen delivered[W] Two cassettes per dosing interval[N] Reminder to load and administer the second cassette within the dosing regimen[I]
Red	Pulsing LEDs encoding error code for diagnosis and correction	Loss of connection to a cloud server	Detailed error information[W] Value of connected data[I] Steps to re-establish connection[T]

I = instructional content, W = warning content, T = troubleshooting content, N = informational content

Another aspect of the invention provides a system for guiding a user of a medicament delivery device to use the medicament delivery device. The system comprises an electronic device. The electronic device 100 comprises a processor 120 configured to operate the method as mentioned above; a memory 130 coupled to the processor 120; at least one of a light sensor 111, an image sensor 112 and a sound sensor 113, and a user interface 140.

In one example, the system further comprises a medicament delivery device 200' comprises a light emitter 213', e.g., LED light, an image indicator 211, e.g., icons, a speaker 212', and a processor 250'. The medicament delivery device 200' comprises at least one medicament container 220' and a delivery powerpack 230. In one example, the medicament container 220' is packed in a cassette that is releasably attached to a reusable part of the medicament delivery device 200'. In this example, the electronics and the delivery powerpack 230 are positioned within the reusable part of the medicament delivery device 200'. In a preferred example, one cassette is capable of containing multiple medicament containers containing with the same or different medicaments. In one example, the medicament delivery device is capable of being attached with one or more cassette. In one example where the medicament delivery device comprises multiple medicament containers containing with different medicaments respectively, the medicaments may be configured to be delivered to the patient in a predetermined sequence. In one example, the delivery powerpack is a motor, preferably, a stepper motor; or the powerpack is a pneumatic pump, e.g., an air pump. In a preferred example, the medicament delivery device 200' comprises a battery 260' and a communication unit 240'.

In one example, the medicament delivery device 200' comprises the information regarding the interpretation of the indications that the medicament delivery device 200' can provide, the user operation manual of the medicament delivery device, and the information related to the medicament. In this example, the communication unit 240' of the medicament delivery device 200' can send the information to the communication unit 150 of the mobile device 100 when the user establishes a

communication between the medicament delivery device 200' and the mobile device 100.

In one example, the medicament delivery device 200' comprises electronics that can output the indication, e.g., light, sound, or images, carrying encoded information. In another example, the medicament delivery device 200' comprises electronics that can provide at least one of a subvisible light signal, and a subaudible sound signal.

Figure 6 illustrates a system for detecting a status of a medicament delivery device 500, according to an example embodiment. The medicament delivery device 500 may include one or more of the features of the medicament delivery devices 200, 200' as discussed above. In particular, as seen in Figure 6, a medicament delivery device 500 is provided that accepts a syringe 502 filled with medication in a known orientation. The known orientation is based on aspects of the syringe geometry or syringe features, such as the syringe flange, outer window, or luer connection.

The medicament delivery device 500 is provided with a window 504 to view an enclosed syringe 502 (and particularly, the syringe plunger 503), once installed in the medicament delivery device 500. The window 504 provided in the housing 506 of the medicament delivery device 500 allows viewing the enclosed syringe 502 in the predetermined operational position. At least part of the syringe 502 remains visible while the medicament delivery device 500 operates such that a user can visually inspect the progress of the infusion. The window 504 has one or more visual features 508 distinguishable by the electronic device 100, as described later. Importantly, visual features 508 are pre-determined dimension, shape, and placement relative to each other and the syringe 502 once placed in the medicament delivery device 500.

As both the syringe 502 and device window 504 features are placed in a known, pre-determined position, and the manufacturing tolerances on syringes (being molded parts) are quite accurate, these cooperating components may provide a reference on progress of the syringe plunger 503 movement when viewed relative to each other.

This construct may be viewed by a field of view 510 of the electronic device 100 (e.g., a camera-enabled smartphone as a non-limiting example) and cooperating software on the electronic device 100. Preferably, software consists of a companion software application that are common for specialty pharmaceuticals, but the software may alternatively be another software application, web interface, or other suitable software.

The software is pre-provided with information about a syringe geometry used with the medicament delivery device 500 and characteristics of the window 504 size, shape, and visual features. Importantly, the pre-provided information includes characteristics of the syringe 502 and window 504 geometries relative to each other when the syringe 502 is installed and the window 504 covers the syringe during medication delivery. Additionally, the pre-provided information need not include the scale markings on the syringe itself, and instead may rely only on the structural features of the medicament delivery device 500.

Regardless of the software implementation, the electronic device 100 captures photographic or videographic data of the syringe 502, syringe stopper 503, device window 504, and visual features 508 located on, in, and/or around the device window 504. Such capture may take place repeatedly at different times during medication delivery, and thus, preferably time-series metadata is captured along at each instance.

Captured data is collected by the software application for later analysis and presented to a user in a easily understood format as described below. Using the approach described herein, either or both of instantaneous or time-series comparisons may be used, each providing different types of useful information to a user of the medicament delivery device 500.

Notably, connectivity between the medicament delivery device 500 and the electronic device 100 is not required for the present method to function. Connectivity

may be provided for other functions, such as adherence monitoring, but a connected device is not required for the present invention. This greatly simplifies the medicament delivery device 500, and provides a pathway for connected-like functionality without device redesign or revalidation.

Moreover, this functionality can be implemented in current medicament delivery devices with minimal modification, provided the medicament delivery device has a viewing window or similar visual or audible indicators from which the status of the medicament delivery device, e.g. ready for use, progress of delivery and/or end of delivery, can be derived.

As discussed previously, the present disclosure does not rely on the printed scale markings on a syringe used with the medicament delivery device 500. Instead, as seen in Figures 6, visual feautures 508 are provided that establish a visual reference point more easily discerned by cooperating software.

The visual feautures 508 can be colored “inserts” that are molded, glued, or snapped into pre-molded areas of the device windows. Colors may obviously be varied, either for human user intuitiveness, or to improve the accuracy of a machine vision system. Shapes may similarly be selected to improve the accuracy of a software vision system.

Such a configuration takes advantage of the inherent accuracy of molded parts to locate each visual feauture 508, and allows customization of the design of the visual features 508 for a specific situation (brand colors for a drug or pharmaceutical company, drug dispensing characteristics, syringe fill, user population, etc.) without changing the underlying pump design, function, or molds.

In one embodiment, the visual features 508 may be a shape (e.g., triangle as shown, or a square, circle, diamond, oval, or other shape) that have no inherent human-readable value. To improve intuitiveness, the visual features 508 may also be

provided as “Harvey Balls” that are progressively filled towards the luer end of the syringe (e.g., 25/50/75/100%).

Any of the visual features 508 may also have human-readable information, such as numeric percentage, mL volume, or other indicia. For instance, the visual features 508 may be molded into the shape of a specific number or may be the same shape and then pad printed. This is particularly valuable for prefilled syringes used with the pump, since these presentations ordinarily do not have scale markings provided. Alternatively, the visual features 508 may be molded, and the indicia (color, shape, numerals, etc.) as described previously may be provided on the device housing surface, as by pad printing, in mold decoration, or other techniques. In all these instances, provision of human-readable information may be used to show progression regardless of whether a companion software application is used.

Figure 7 shows a syringe 602 installed in the representative medicament delivery device 600. As shown in Figure 7, the housing 606 of the the medicament delivery device 600 incldues a window 604, tapering down in width from left to right (i.e., in the direction of the movement of the stopper 603 during drug delivery). This tapered window 604 provides an example of a readily identifiable shape for the electronic device 100, also allowing discernment of the device orientation.

The window, however, need not be shaped as in Figure 7. A symmetric window may be provided with indicators, as shown and described above in relation to Figure 6.

Obviously, combinations of any of the indicator aspects described above may also be used in combination to best balance machine vision accuracy and high patient/healthcare personnel usability.

Scenario 1 – Instantaneous Measurement

The simplest scenario for use of the apparatus described above is at a single time point during administration. Any single photograph or video capture may be used by the software to infer the current state of medication delivery as follows:

1. **Prompt to capture visual information.** The companion software application may be configured to remind a user of the apparatus to capture visual information at one or more time points. In one preferred embodiment, the first prompt is taken at the beginning of administration. In another preferred embodiment, the prompts are made periodically, for instance, every 15 minutes in a one-hour period, or every 10 minutes in a half-hour period.

2. **Visual information capture.** The camera captures photographic or videographic data of the syringe, syringe stopper, device window, and visual features located on, in, and/or around the device window. Such data is optionally tagged with timestamp metadata for later analysis as described in Scenario 1.

3. **Device orientation determination.** One or more virtual features of the medicament delivery device or medicament delivery device window are used to determine known reference points and determine orientation of the device relative to the camera capturing the visual data, optionally also compensating for angulation, rotation, or optical artifacts such as parallax.

4. **Syringe stopper identification.** Within the medicament delivery device window, the position of the syringe stopper is identified relative to the device window and any visual feature(s). This is easily performed with edge detection software, as the stopper is comparatively darker and opaquer compared to the syringe, which is light and translucent.

5. **Stopper position in syringe is inferred.** As described previously, the syringe and window positions are pre-determined relative to each other. Thus, identifying the stopper position within the window also allows inference of its instantaneous position within the syringe, and thus the current volume of medication administered or remaining.

6. **Instantaneous syringe volume inferred.** As the syringe size is known a priori, stopper position determines the instantaneous syringe volume at the time of the photograph.

7. **Instantaneous syringe volume communicated.** This is calculated by the companion software application and displayed to a user of the device, as on a smartphone. This step is analogous to the user reading a scale marking on the syringe. Notably, this step provides human readable format even if the on-syringe scale is not visible, or not present.

8. **Instantaneous syringe volume stored.** The inferred syringe volume of Step 6 may be stored in the companion software application along with time metadata of Step 2 as a volume-time datapoint for subsequent use as described below in Scenario 2.

If the fill volume of the syringe is known in advance the instantaneous syringe volume inferred may be used to optionally communicate additional detail to a user of the device:

9. **Volume administered thus far.** The starting volume is compared to the instantaneous volume of Step 6. The display of Step 7 is augmented with a display of the volume administered or as a percent complete.

10. **Volume remaining.** The starting volume is compared to the instantaneous volume of Step 6. The display of Step 7 is augmented with a display of the volume remaining (or percent remaining).

11. **Time remaining.** If the average rate of the pump and fluidic system is known in advance, the comparison from Step 10 may be used (along with the average rate) to provide a time estimate to a user of the device. This estimate may be provided as a single point estimate (i.e., volume remaining ÷ average flow rate). Alternatively, the companion software application may be configured to display the time estimate as a range, especially if the software application is pre-programmed with a tolerance on the average flow rate.

Scenario 2 – Time-Series Comparisons

While a single instance capture described above provides useful information to a user of the medicament delivery device, additional useful information may also be provided if a user captures multiple device state snapshots over the course of an infusion, as described in Scenario 1, Step 8. Comparisons may be pairwise in time or may be trended across one or more time series.

Certain readings may also be included or excluded; for instance, two nearby snapshots may be treated as a single reading, may be averaged, or one may be excluded, especially if flow rates (and thus stopper movement) are small. Preferably, each snapshot used is each at a different discrete position, as this maximizes the information that may be extracted, especially for longer injection times.

Regardless, by comparing one or more snapshots using time metadata, stopper movement relative to the visual features may be compared by the companion app, giving users “virtual” in process feedback in in various useful ways beyond Scenario 1.

In the simplest case, relating displacement between two or more instantaneous snapshots in conjunction with time metadata yields an approximate average rate. Calculation of a trailing average provides a forecast of approximate time remaining, or a trend/graph of rate versus time.

By extension, strings of multiple images in the form of videos or time-lapse sequences may be analyzed frame-by-frame or frames sampled for greater data collection frequency if desired. This is particularly advantageous if prompts are supplied to the user, as in Step 1 of Scenario 1.

Once calculated, the average rate is then communicated visually to a user of the companion software application or device, along with different inferences made from the data.

Calculation of these parameters also allows detection of undesired or unsafe conditions, especially that can be inferred from changes to flow rate.

For instance, a rapid decrease in average rate may prompt a warning on the companion software application to check for tubing set occlusion, as by inadvertent closure of the tubing set clamp or tangling of the tubing set.

Conversely, a rapid increase in average rate could prompt a warning that there is a leak or disconnection in a fluidic connection, or removal of a needle from an injection site. Notably, these situations are not easily detectible simply by a user visually observing stopper movement in a syringe at a single point in time but are easily discerned by software.

Scenario 3 – Comparison to Expected Delivery Profile

Figure 8 shows an illustrative example of a complete delivery profile for a representative device that may be used in early clinical trials or commercially approved molecules. For instance, known devices may include a constant pressure pump with mechanical (spring drive) and has a delivery profile shown in Figure 8 when tested with 60mL of water. Notably, the flow behavior may be different with non-Newtonian biologic medications. The startup behavior is visible at the left side (e.g., 0-1 min), and steady state behavior is visible as time progresses (e.g., 2-28

min). The fluidic path used in this example incorporates a reduced-diameter tubing segment that allows for approximately 120mL/h.

It is worth highlighting that although the axes of the plot in Figure 8 are Flow Rate and Time, the device used to generate the graph shown in Figure 8 is a pressure-regulated device (as it is driven via spring). The data would look different if the drug dispensed has a different viscosity than water, or if the needle were elevated relative to the device (increasing head pressure), as the resultant flow rate would change. The device's driving pressure, however, would not be impacted by these variables, as the device is fundamentally pressure-regulated via its drive spring.

As this behavior is inherent to each pump and a specific fluid (in this case, saline), the companion software application may be pre-provisioned with one or more profiles, each corresponding to a specific pump and fluid (such as a biologic medication). Optionally, such information may also be provided versus temperature, either as discrete curves or a surface plot.

It is apparent that the data inferred from Scenarios 1 & 2 may be "anchored" or plotted on a chart such as Figure 8. This enables additional useful information to be provided to a user of the apparatus beyond that discussed in Scenarios 1 & 2.

Calculations of instantaneous flow rate may be compared to a pump and drug-specific flow vs. time curve to confirm that the flow rate is "on track" or "as expected." For instance, if an instantaneous flow rate measured at 20 minutes into infusion was approximately 125 ml/hr using the curve of Figure 8, and the total volume was 60mL at the outset, the system could provide a refined time remaining estimate to a user (in this case, about 10 minutes longer).

Conversely, if the inferred flow rate were lower at several points on the baseline (e.g., room temperature) curve, the companion software application could estimate a longer time (e.g., 15 minutes) based on a "search" through the temperature-flow-time

curves to match the observed flow rates, thus inferring the medication temperature from the inferred flow rate.

Since some medications, such as biologic medications, display temperature-viscosity sensitivity, the curve of Figure 8 will shift (i.e., vary) based on temperature. The companion application, by comparing observed time-series data to expected pre-configured room-temperature data, can develop a patient-specific calculation predicting behavior of the medicament delivery device, e.g., estimated infusion duration. This is useful for patients that live in different climes, or those that prefer not to warm medication prior to administration to reduce total duration of the process.

Scenario 4 – Comparison to Device Shape

Although a rigid plastic syringe is the focus of this disclosure, the same concept may be applied to other situations where a recognizable shape change of the medicament delivery device takes place during the delivery. For instance, elastomeric pumps have many of the same elements of a constant pressure pump. These systems, like syringe pumps described above, feature a hydraulic restrictor and fixed volume reservoir that is compressed by an elastomeric bladder or element to motivate fluid flow. Figures 9A-9C shows a simple elastomeric pump 700, where a central medication reservoir is inside an expandable elastomeric bladder 702. The elastomeric pump 700 takes on a distinctive shape at each stage of medication delivery as seen from Figures 9A-9C. Other more complicated designs are possible as well, such as a medicament delivery device in which the medication reservoir is compressed similarly to a syringe. In each of these cases, the distinctive relative motion of the components may be detected and analyzed by the electronic device 100, akin to measurement of stopper movement relative to fixed reference points, as described above.

The medicament delivery devices described herein can be used for the treatment and/or prophylaxis of one or more of many different types of disorders. Exemplary

disorders include but are not limited to: rheumatoid arthritis, inflammatory bowel diseases (e.g. Crohn's disease and ulcerative colitis), hypercholesterolaemia, diabetes (e.g. type 2 diabetes), psoriasis, migraines, multiple sclerosis, anaemia, lupus, atopic dermatitis, asthma, nasal polyps, acute hypoglycaemia, obesity, anaphylaxis and allergies. Exemplary types of drugs that could be included in the medicament delivery devices described herein include, but are not limited to, small molecules, hormones, cytokines, blood products, antibodies, antibody-drug conjugates, bispecific antibodies, proteins, fusion proteins, peptibodies, polypeptides, pegylated proteins, protein fragments, protein analogues, protein variants, protein precursors, chimeric antigen receptor T cell therapies, cell or gene therapies, oncolytic viruses, or immunotherapies and/or protein derivatives. Exemplary drugs that could be included in the medicament delivery devices described herein include, but are not limited to (with non-limiting examples of relevant disorders in brackets): etanercept (rheumatoid arthritis, inflammatory bowel diseases (e.g. Crohn's disease and ulcerative colitis)), evolocumab (hypercholesterolaemia), exenatide (type 2 diabetes), secukinumab (psoriasis), erenumab (migraines), alirocumab (rheumatoid arthritis), methotrexate (amethopterin) (rheumatoid arthritis), tocilizumab (rheumatoid arthritis), interferon beta-1a (multiple sclerosis), sumatriptan (migraines), adalimumab (rheumatoid arthritis), darbepoetin alfa (anaemia), belimumab (lupus), peginterferon beta-1a' (multiple sclerosis), sarilumab (rheumatoid arthritis), semaglutide (type 2 diabetes, obesity), dupilumab (atopic dermatitis, asthma, nasal polyps, allergies), glucagon (acute hypoglycaemia), epinephrine (anaphylaxis), insulin (diabetes), atropine and vedolizumab (inflammatory bowel diseases (e.g. Crohn's disease and ulcerative colitis)) , ipilimumab, nivolumab, pembrolizumab, atezolizumab, durvalumab, avelumab, cemiplimab, rituximab, trastuzumab, ado-trastuzumab emtansine, fam-trastuzumab deruxtecan-nxki, pertuzumab, transtuzumab-pertuzumab, alemtuzumab, belantamab mafodotin-blmf, bevacizumab, blinatumomab, brentuximab vedotin, cetuximab, daratumumab, elotuzumab, gemtuzumab ozogamicin, 90-Yttrium-ibritumomab tiuxetan, isatuximab, mogamulizumab, moxetumomab pasudotox, obinutuzumab, ofatumumab,

olaratumab, panitumumab, polatuzumab vedotin, ramucirumab, sacituzumab govitecan, tafasitamab, or margetuximab. Pharmaceutical formulations including, but not limited to, any drug described herein are also contemplated for use in the medicament delivery devices described herein, for example pharmaceutical formulations comprising a drug as listed herein (or a pharmaceutically acceptable salt of the drug) and a pharmaceutically acceptable carrier. Pharmaceutical formulations comprising a drug as listed herein (or a pharmaceutically acceptable salt of the drug) may include one or more other active ingredients, or may be the only active ingredient present.

Exemplary drugs that could be included in the medicament delivery devices described herein include, but are not limited to, an immuno-oncology or bio-oncology medications such as immune checkpoints, cytokines, chemokines, clusters of differentiation, interleukins, integrins, growth factors, enzymes, signaling proteins, pro-apoptotic proteins, anti-apoptotic proteins, T-cell receptors, B-cell receptors, or costimulatory proteins.

Exemplary drugs that could be included in the medicament delivery devices described herein include, but are not limited to, those exhibiting a proposed mechanism of action, such as HER-2 receptor modulators, interleukin modulators, interferon modulators, CD38 modulators, CD22 modulators, CCR4 modulators, VEGF modulators, EGFR modulators, CD79b modulators, Trop-2 modulators, CD52 modulators, BCMA modulators, PDGFRA modulators, SLAMF7 modulators, PD-1/PD-L1 inhibitors/modulators, B-lymphocyte antigen CD19 inhibitors, B-lymphocyte antigen CD20 modulators, CD3 modulators, CTLA-4 inhibitors, TIM-3 modulators, VISTA modulators, INDO inhibitors, LAG3 (CD223) antagonists, CD276 antigen modulators, CD47 antagonists, CD30 modulators, CD73 modulators, CD66 modulators, CDw137 agonists, CD158 modulators, CD27 modulators, CD58 modulators, CD80 modulators, CD33 modulators, APRIL receptor modulators, HLA antigen modulators, EGFR modulators, B-lymphocyte cell adhesion molecule modulators, CDw123 modulators, Erbb2 tyrosine kinase receptor modulators,

mesothelin modulators, HAVCR2 antagonists, NY-ESO-1 OX40 receptor agonist modulators, adenosine A2 receptors, ICOS modulators, CD40 modulators, TIL therapies, or TCR therapies.

Exemplary drugs that could be included in the medicament delivery devices described herein include, but are not limited to, a multi-medication treatment regimen such as AC, Dose-Dense AC, TCH, GT, EC, TAC, TC, TCHP, CMF, FOLFOX, mFOLFOX6, mFOLFOX7, FOLFCIS, CapeOx, FLOT, DCF, FOLFIRI, FOLFIRINOX, FOLFOXIRI, IROX, CHOP, R-CHOP, RCHOP-21, Mini-CHOP, Maxi-CHOP, VR-CAP, Dose-Dense CHOP, EPOCH, Dose-Adjusted EPOCH, R-EPOCH, CODOX-M, IVAC, HyperCVAD, R-HyperCVAD, SC-EPOCH-RR, DHAP, ESHAP, GDP, ICE, MINE, CEPP, CDOP, GemOx, CEOP, CEPP, CHOEP, CHP, GCVP, DHAX, CALGB 8811, HIDAC, MOpAD, 7 + 3, 5 +2, 7 + 4, MEC, CVP, RBAC500, DHA-Cis, DHA-Ca, DHA-Ox, RCVP, RCEPP, RCEOP, CMV, DDMVAC, GemFLP, ITP, VIDE, VDC, VAI, VDC-IE, MAP, PCV, FCR, FR, PCR, HDMP, OFAR, EMA/CO, EMA/EP, EP/EMA, TP/TE, BEP, TIP, VIP, TPEx, ABVD, BEACOPP, AVD, Mini-BEAM, IGEV, C-MOPP, GCD, GEMOX, CAV, DT-PACE, VTD-PACE, DCEP, ATG, VAC, VeIP, OFF, GTX, CAV, AD, MAID, AIM, VAC-IE, ADOC, or PE.

Exemplary drugs that could be included in the medicament delivery devices described herein include, but are not limited to, those used for chemotherapy, such as an alkylating agent, plant alkaloid, antitumor antibiotic, antimetabolite, or topoisomerase inhibitor, enzyme, retinoid, or corticosteroid. Exemplary chemotherapy drugs include, by way of example but not limitation, 5-fluorouracil, cisplatin, carboplatin, oxaliplatin, doxorubicin, daunorubicin, idarubicin, epirubicin, paclitaxel, docetaxel, cyclophosphamide, ifosfamide, azacitidine, decitabine, bendamustine, bleomycin, bortezomib, busulfan, cabazitaxel, carmustine, cladribine, cytarabine, dacarbazine, etoposide, fludarabine, gemcitabine, irinotecan, leucovorin, melphalan, methotrexate, pemetrexed, mitomycin, mitoxantrone, temsirolimus, topotecan, valrubicin, vincristine, vinblastine, or vinorelbine.

While various aspects and embodiments have been disclosed herein, other aspects and embodiments will be apparent to those skilled in the art. All embodiments within and between different aspects of the devices and methods can be combined unless the context clearly dictates otherwise. The various aspects and embodiments disclosed herein are for purposes of illustration and are not intended to be limiting, with the true scope and spirit being indicated by the claims.

CLAIMS

1. A method for enabling a user to detect a status of a medicament delivery device, the method comprising:

   capturing at least one of a light signal, an image signal, and an audible signal generated by the medicament delivery device via at least one of a light sensor, an image sensor, and a sound sensor of an electronic device;

   fetching information from a database with the captured signal; and

   providing an indication based on the fetched information to a user of the medicament delivery device via a user interface of the electronic device.

2. The method according to claim 1, wherein the step of capturing at least one of a light signal, an image signal and an audible signal of the medicament delivery device comprises a step of:
   capturing at least one of a subvisible light signal and a subaudible sound signal generated by the medicament delivery device.

3. The method according to claim 2, wherein the at least one of a subvisible light signal and a subaudible sound signal is configured to contain encoded information related to the medicament delivery device.

4. The method according to any one of the preceding claims, further comprising a step of selecting a type of indications to be provided to the user based on inputted user information.

5. The method according to any one of the preceding claims, wherein after the step of providing an indication based on the fetched information to a user of the medicament delivery device the method further comprises the following

steps in the following order: repeating all operated steps in the same operated order.

6. The method according to any one of the preceding claims, wherein the indication provided to the user is presented to the user with at least one of text message, voice message, animation, and a vibration indication.

7. The method according to any one of the preceding claims, wherein the indication provided to the user comprises content related to the medicament delivery device, and wherein the content comprises at least one of instructional content, warning content, troubleshooting content, and informational content.

8. The method according to any one of the preceding claims, wherein the step of fetching information from a database with the captured signal comprises the following steps in the following order:
searching information from the database stored in a memory of the electronic device;
matching the information with the captured signal; and
retrieving the matched information.

9. The method according to any one of claims 1-7, wherein the step of fetching information from a database with the captured signal comprises the following steps in the following order:
sending a request with the captured signal with a communication unit of the electronic device;
receiving the information from a server connected to the database with the communication unit of the electronic device.

10. The method according to any of the preceding claims, wherein the method is configured to be operated by a processor of an electronic device, and wherein the electronic device comprises a memory coupled to the processor, at least one of a light sensor, an image sensor and a sound sensor, and a user interface.

11. The method according to claim 10, wherein the electronic device is a mobile device.

12. The method according to claim 11, wherein before the step of capturing at least one of a light signal, an image signal and an audible signal of the medicament delivery device, the method comprises a step of: receiving an activation signal from an action of a user on the user interface or a wirelessly transmitted activation signal.

13. The method according to any of the preceding claims, wherein the step of capturing at least one of a light signal, an image signal and an audible signal of the medicament delivery device comprises a step of:
capturing a position of one or more visual features positioned on the medicament delivery device to thereby determine an orientation of the medicament delivery device.

14. The method according to any of the preceding claims, wherein the step of capturing at least one of a light signal, an image signal and an audible signal of the medicament delivery device comprises a step of:
capturing photographic or videographic data of a syringe, a syringe stopper, a device window, and/or one or more visual features located on, in, and/or around the device window of the medicament delivery device.

15. The method according to any of the preceding claims, wherein the step of fetching information from a database with the captured signal comprises:
fetching a stored drug delivery profile corresponding to a medicament in the medicament delivery device; and
comparing a measured drug delivery profile to the stored drug delivery profile to thereby provide the indication based on the fetched information to the user of the medicament delivery device via the user interface of the electronic device.

16. The method according to any of the preceding claims, wherein the step of capturing at least one of a light signal, an image signal and an audible signal of the medicament delivery device comprises a step of:
capturing photographic or videographic data of a size and/or shape of the medicament delivery device during delivery.

17. A system for guiding a user of a medicament delivery device to use the medicament delivery device, the system comprising an electronic device, the electronic device comprising:
a processor configured to operate the method according to any one of the preceding claims;
a memory coupled to the processor;
at least one of a light sensor, an image sensor, and a sound sensor; and
a user interface.

18. The system according to claim 17, wherein the database is stored in the memory of the electronic device.

19. The system according to claim 18, wherein the database is stored in a remote server, and wherein the processor is configured to establish a communication

with the remote server before operating the method according to any one of the preceding claims.

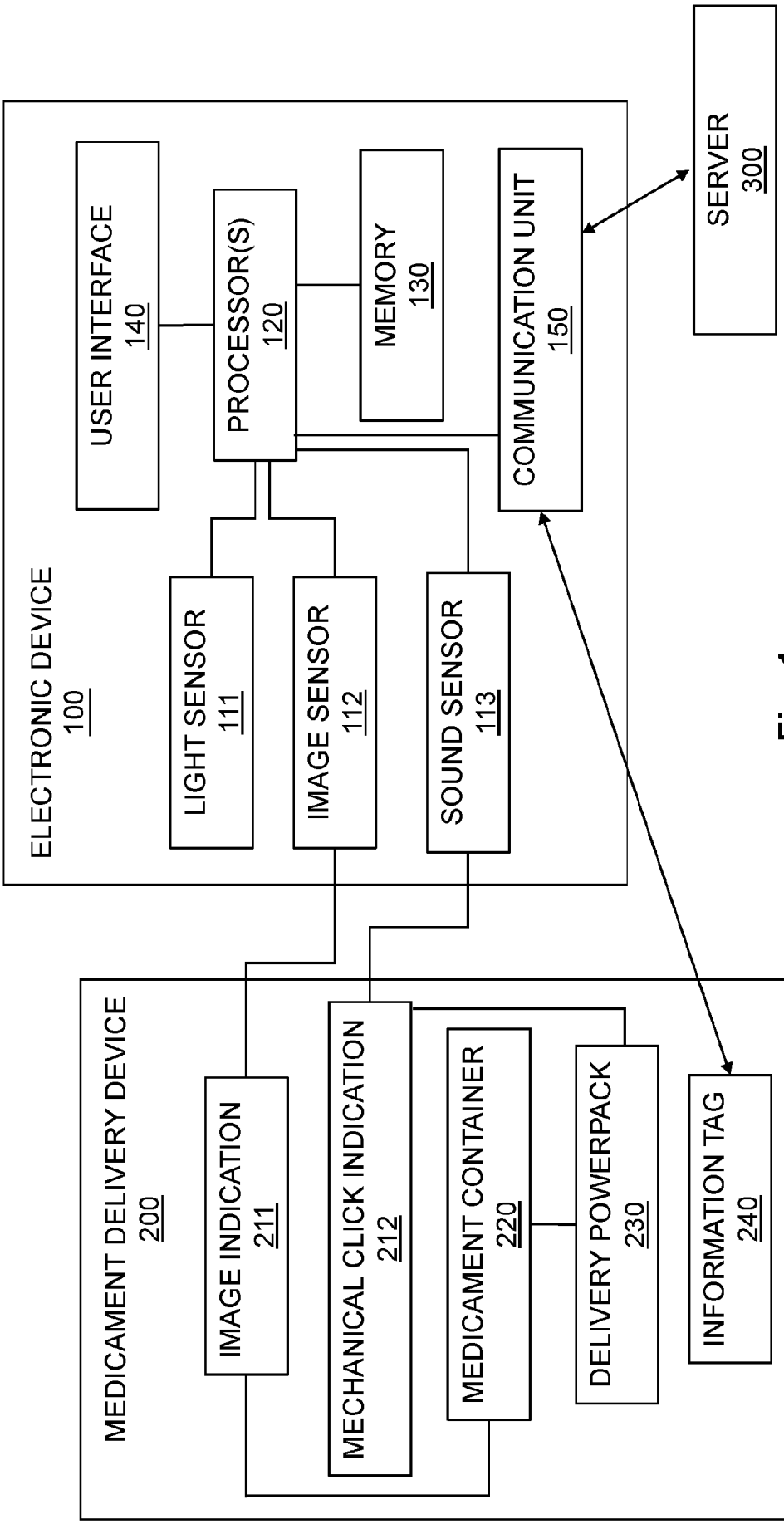
ELECTRONIC DEVICE
100
USER INTERFACE
140
PROCESSOR(S)
120
MEMORY
130
COMMUNICATION UNIT
150
SERVER
300
LIGHT SENSOR
111
IMAGE SENSOR
112
SOUND SENSOR
113
MEDICAMENT DELIVERY DEVICE
200
IMAGE INDICATION
211
MECHANICAL CLICK INDICATION
212
MEDICAMENT CONTAINER
220
DELIVERY POWERPACK
230
INFORMATION TAG
240

Fig. 1

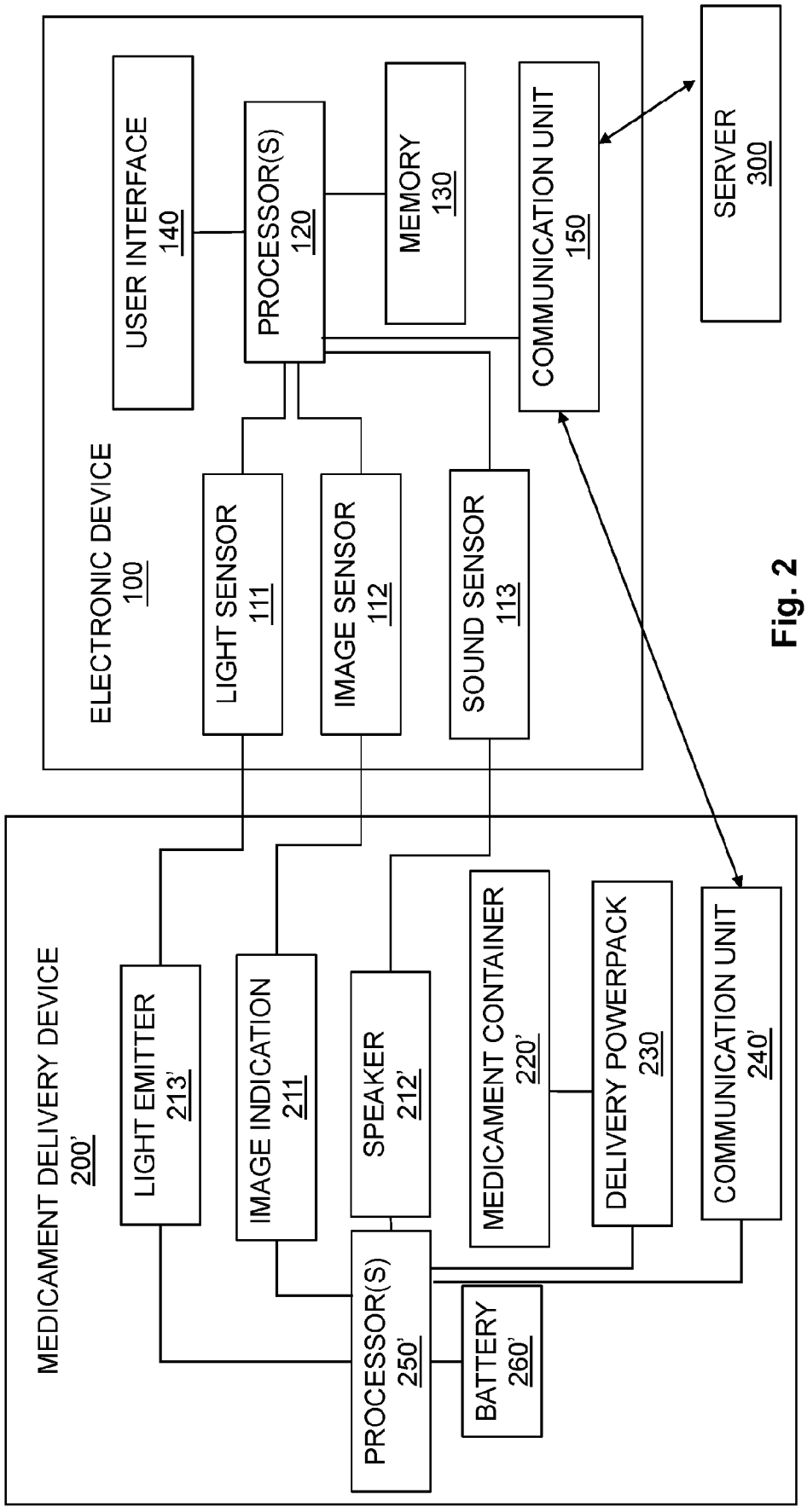
ELECTRONIC DEVICE
100
USER INTERFACE
140
PROCESSOR(S)
120
MEMORY
130
COMMUNICATION UNIT
150
SERVER
300
LIGHT SENSOR
111
IMAGE SENSOR
112
SOUND SENSOR
113
MEDICAMENT DELIVERY DEVICE
200'
LIGHT EMITTER
213'
IMAGE INDICATION
211
SPEAKER
212'
MEDICAMENT CONTAINER
220'
DELIVERY POWERPACK
230
COMMUNICATION UNIT
240'
PROCESSOR(S)
250'
BATTERY
260'

Fig. 2

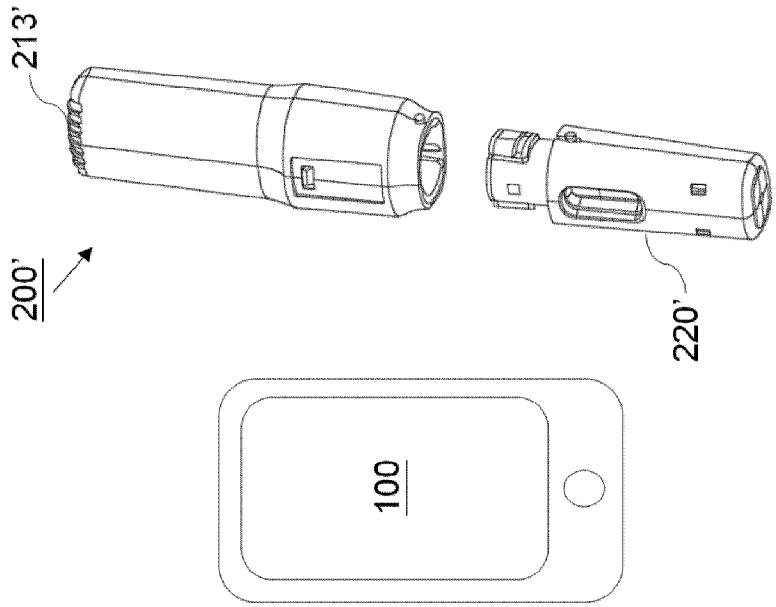

Fig. 4

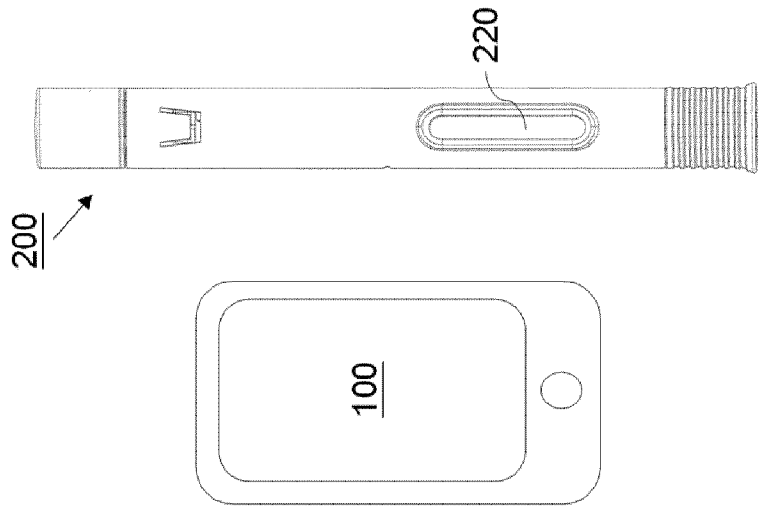

Fig. 3

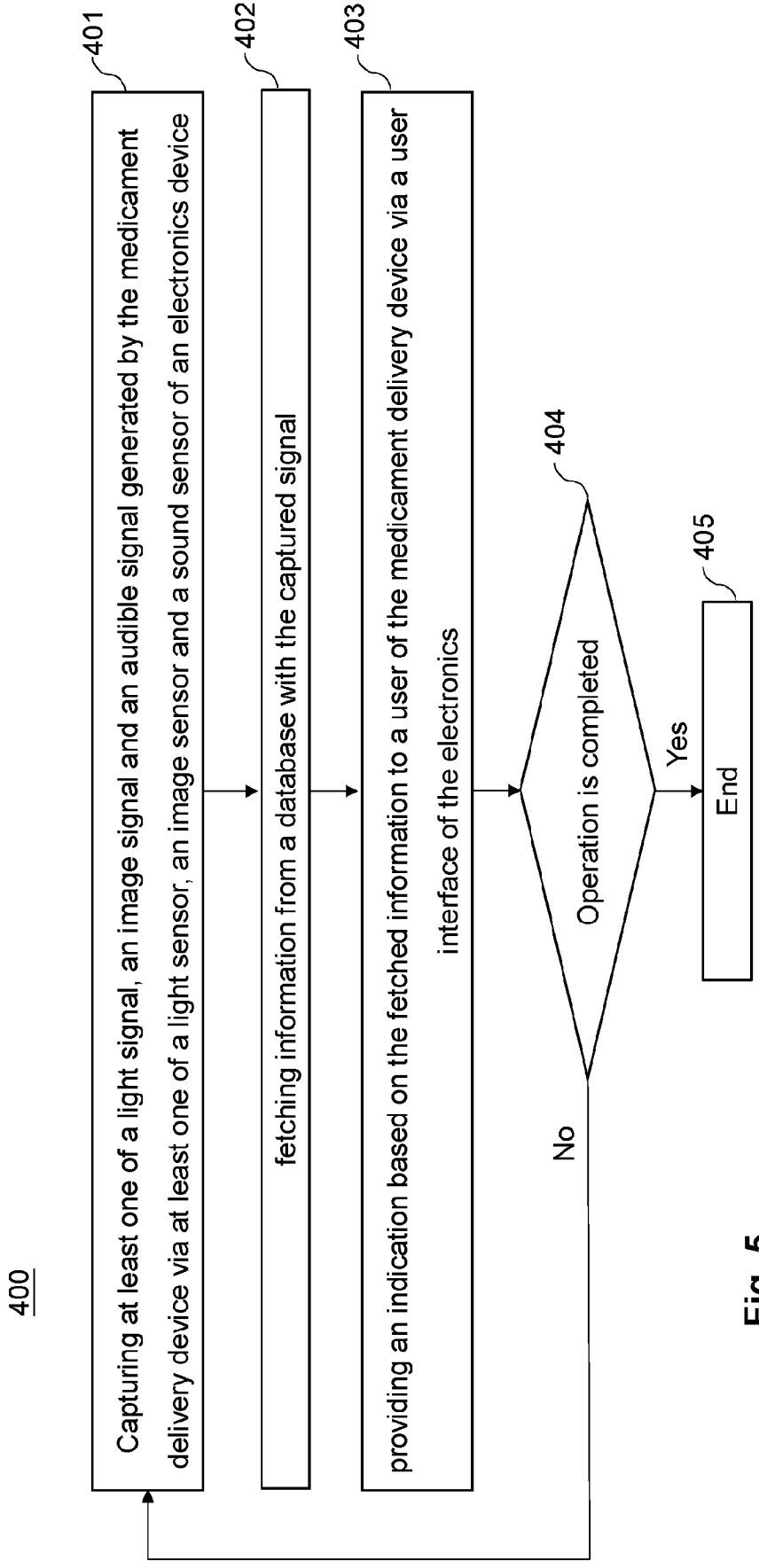
400
401
Capturing at least one of a light signal, an image signal and an audible signal generated by the medicament delivery device via at least one of a light sensor, an image sensor and a sound sensor of an electronics device
402
fetching information from a database with the captured signal
403
providing an indication based on the fetched information to a user of the medicament delivery device via a user interface of the electronics
404
Operation is completed
No
Yes
405
End

Fig. 5

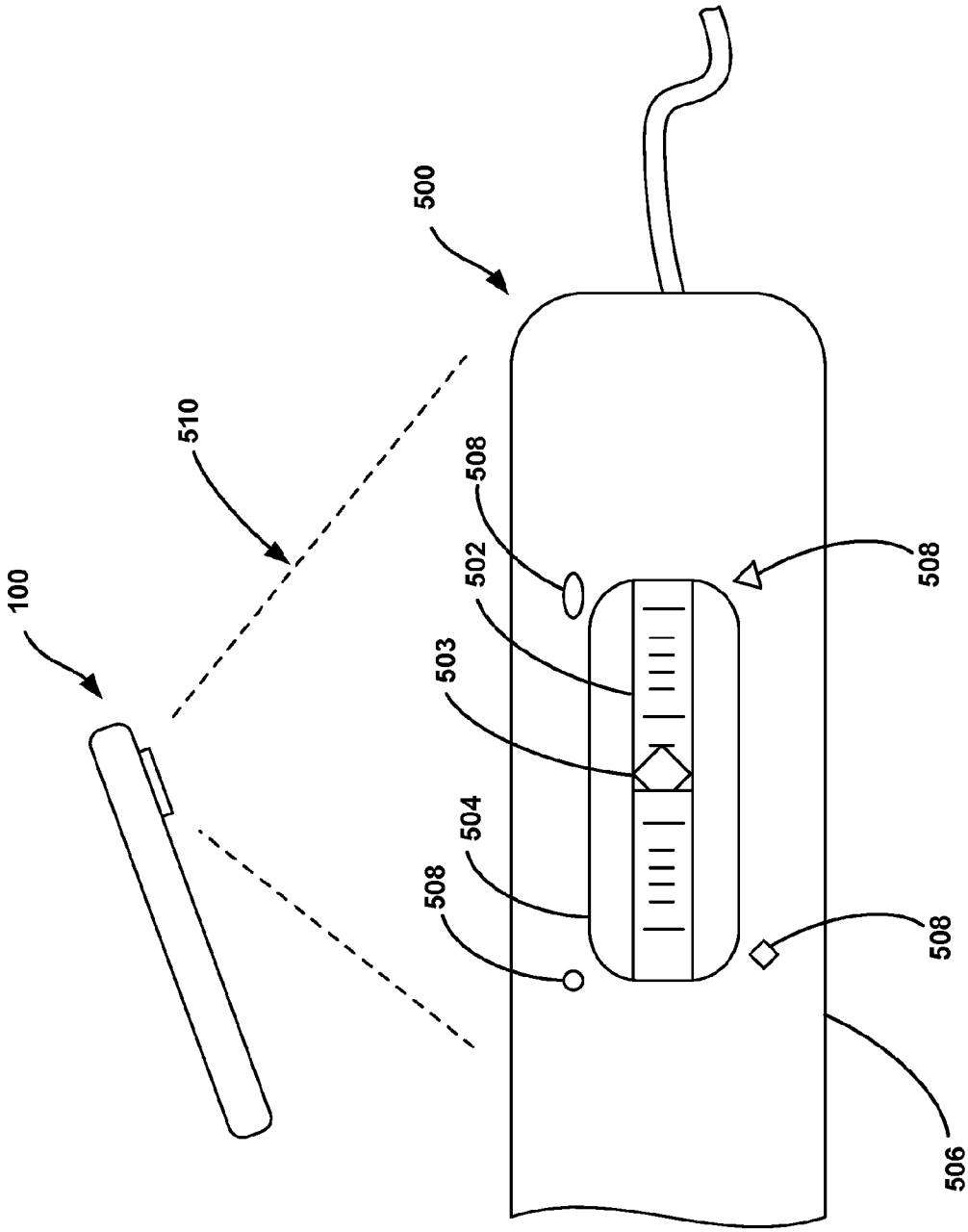

Fig. 6

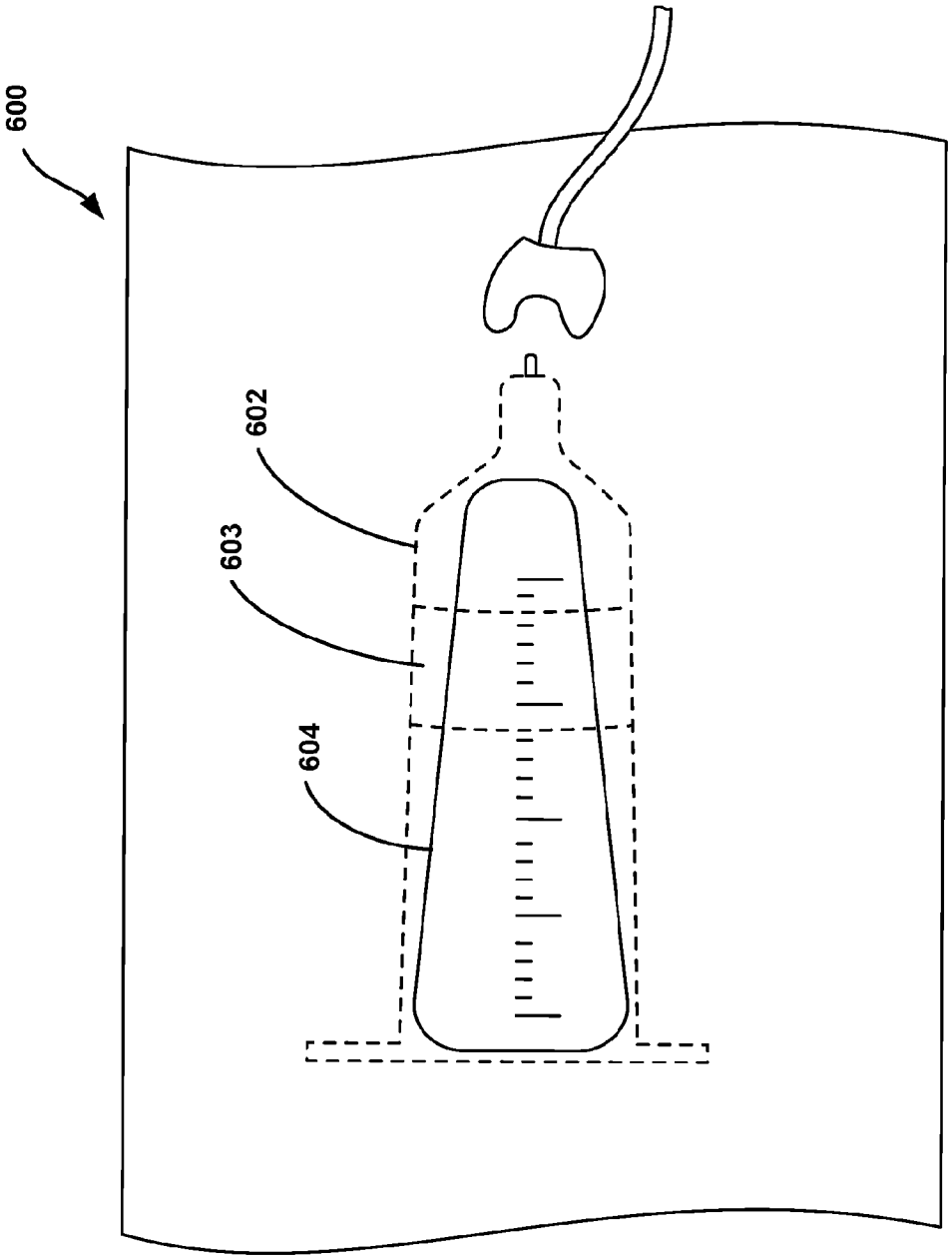

Fig. 7

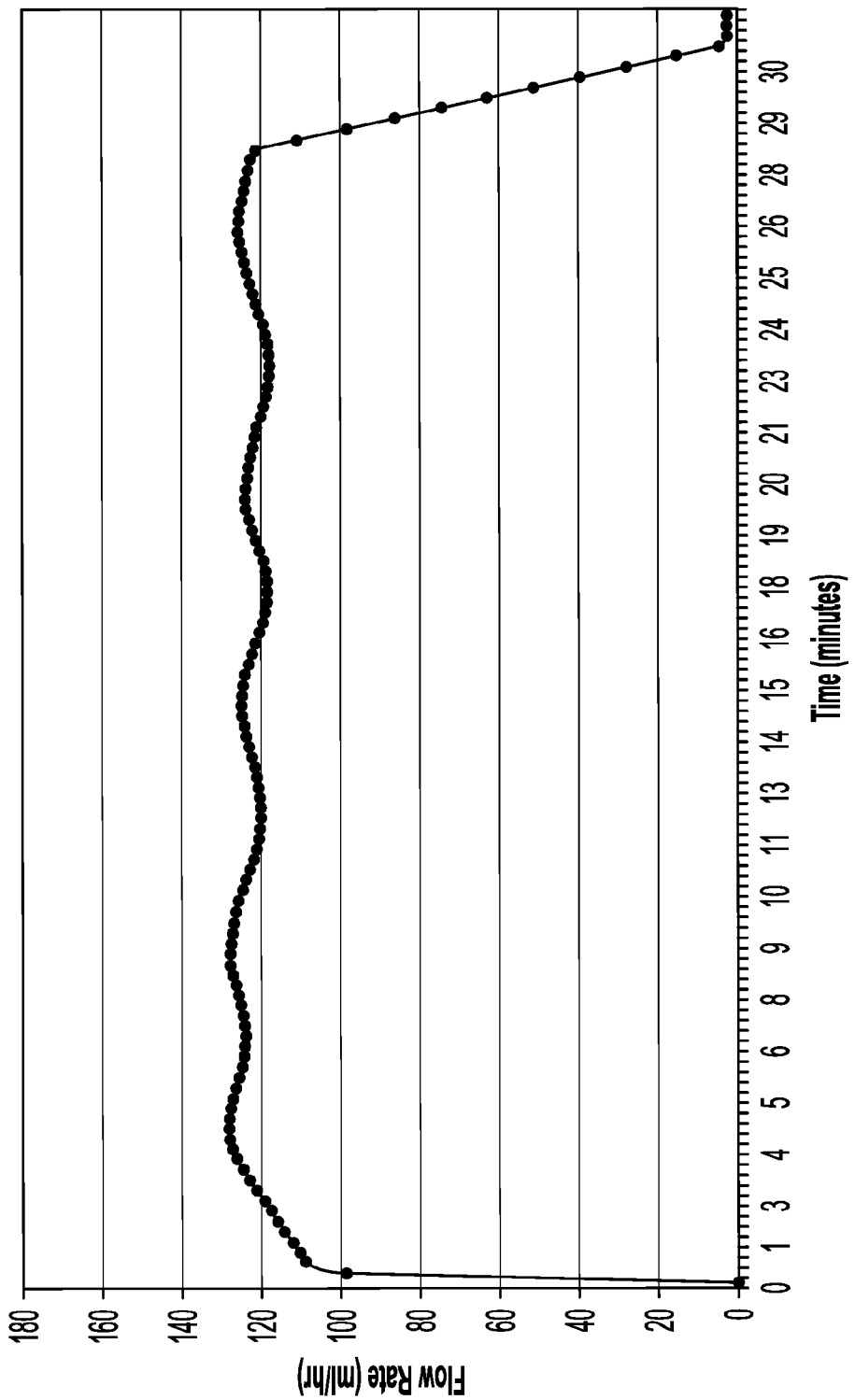
Flow Rate (ml/hr)
0
20
40
60
80
100
120
140
160
180
Time (minutes)
0 1 3 4 5 6 8 9 10 11 13 14 15 16 18 19 20 21 23 24 25 26 28 29 30

Fig. 8

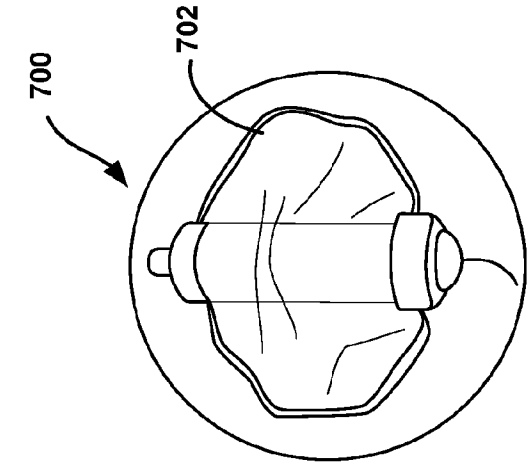

Fig. 9C

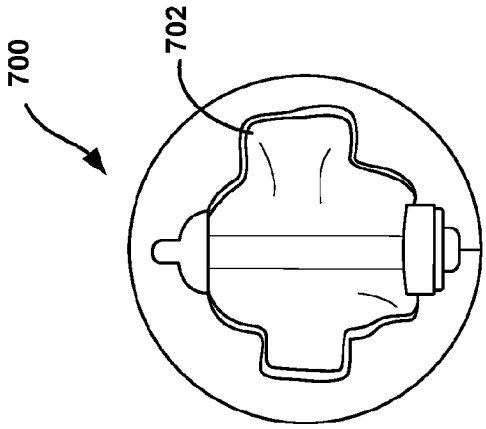

Fig. 9B

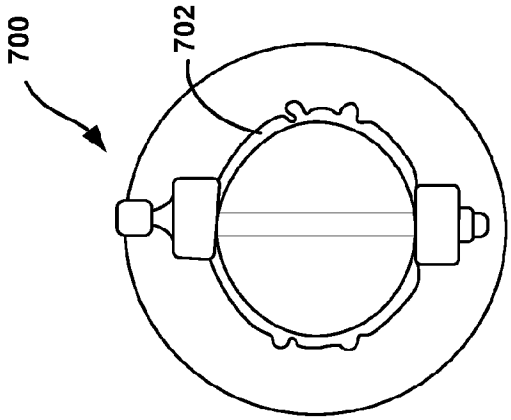

Fig. 9A

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2024/064848

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/172 G16H20/17
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M G16H

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2018/280624 A1 (BITTON GABRIEL [IL] ET AL) 4 October 2018 (2018-10-04) paragraph [0055] - paragraph [0209]; figures 1-25	1-19
X	CA 3 155 914 A1 (JANSSEN PHARMACEUTICALS INC [US]) 1 April 2021 (2021-04-01) paragraph [0073] - paragraph [0230]; figures 1-43	1-19
X	US 9 179 260 B2 (MYLAN INC [US]; MYLAN INC [US]) 3 November 2015 (2015-11-03) page 5, line 44 - page 20, line 10; figures 1-14	1-19

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance;; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 September 2024	26/09/2024

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Knaus-Reinbold, S

1

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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2024/064848

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2018/336962 A1 (CRONIN JOHN [US] ET AL) 22 November 2018 (2018-11-22) paragraph [0037] - paragraph [0051]; figures 1-5 -----	1-19
X	WO 2022/178447 A1 (BETA BIONICS INC [US]) 25 August 2022 (2022-08-25) paragraph [0104] - paragraph [0912]; figures 1-84 -----	1-19

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2024/064848

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