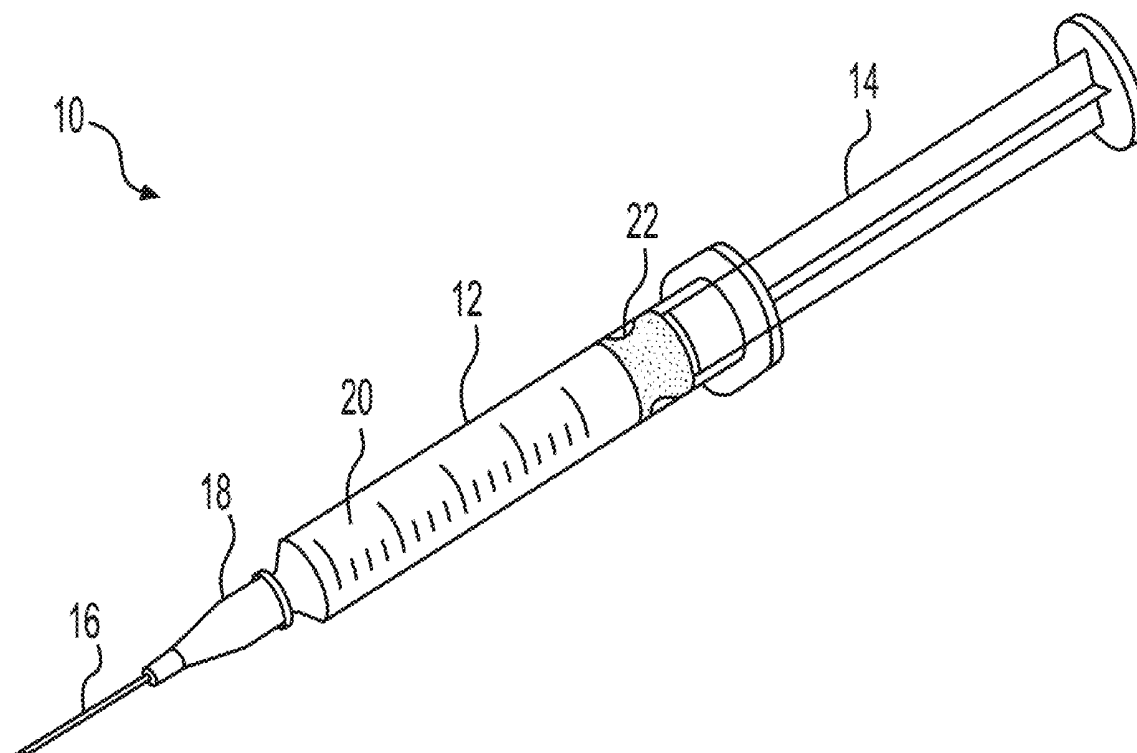


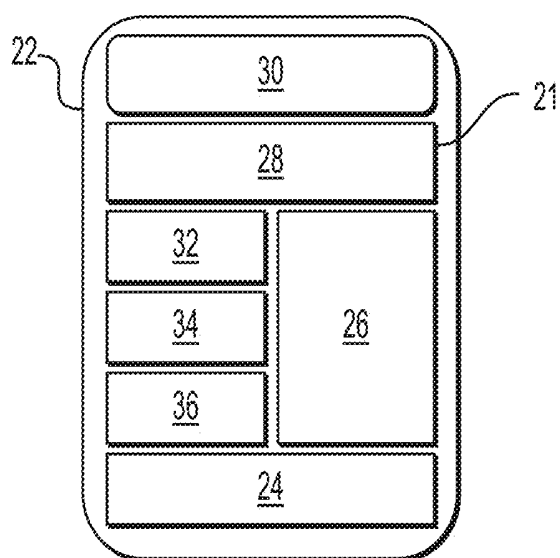
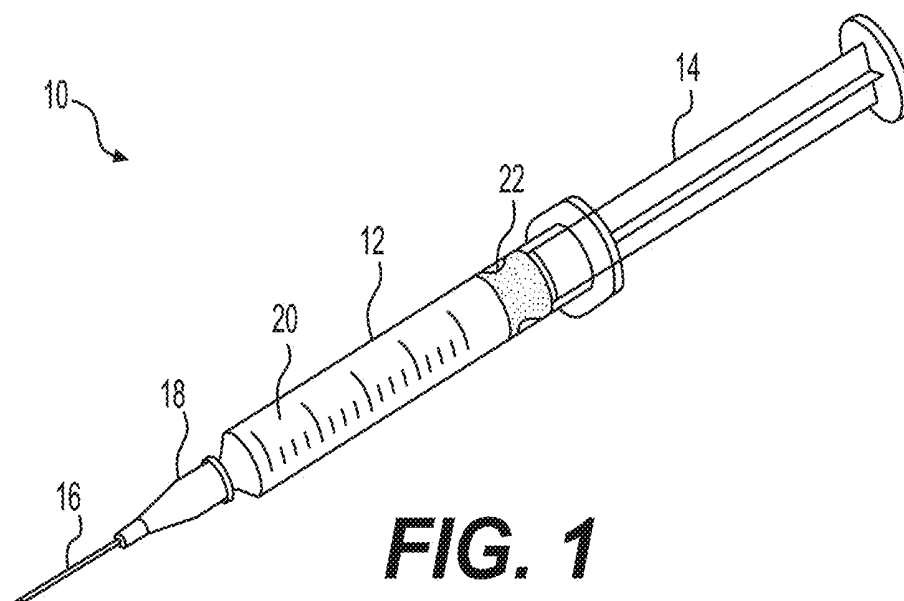


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Krasnow (43) **Pub. Date: Dec. 12, 2019**(54) **ULTRASOUND TRACKING OF
MEDICATION DELIVERY BY MEDICATION
INJECTION DEVICES**(71) Applicant: **Verily Life Sciences LLC**, South San
Francisco, CA (US)(72) Inventor: **Benjamin David Krasnow**, Redwood
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A61B 5/002 (2013.01); **A61B 5/4839**
(2013.01)(57) **ABSTRACT**

A medication injection device includes a plunger head having an elastomer housing that fits within a barrel. The plunger head includes an ultrasonic transducer that sends and receives ultrasonic signals in the form of ultrasonic waves, an antenna, a microcontroller that interfaces with the ultrasonic transducer and the antenna, and a power source that powers the microcontroller and the ultrasonic transducer. The ultrasonic transducer, the antenna, the microcontroller, and the power source may be at least partially encapsulated in the elastomer housing. The microcontroller may be programmed to measure echo times of the ultrasonic waves, compare consecutive echo times, and apply a compensation factor. The microcontroller may also be programmed to calculate a volume of medication dispensed from the barrel.





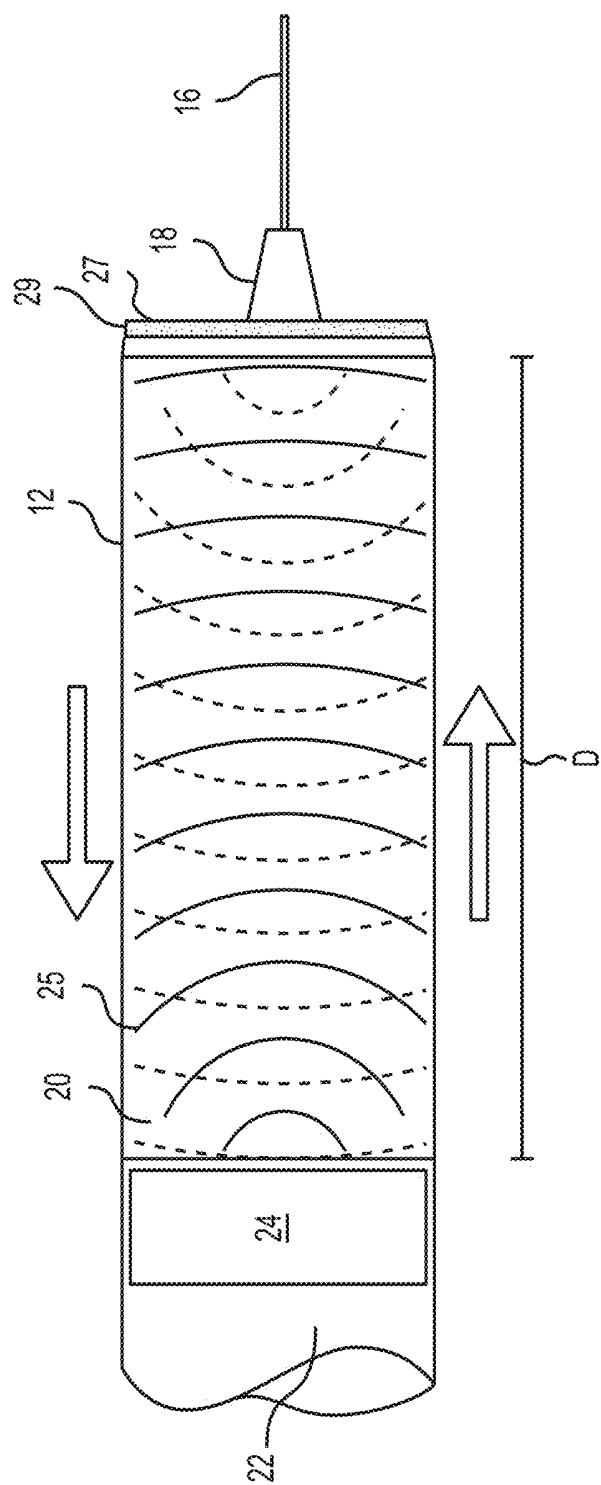
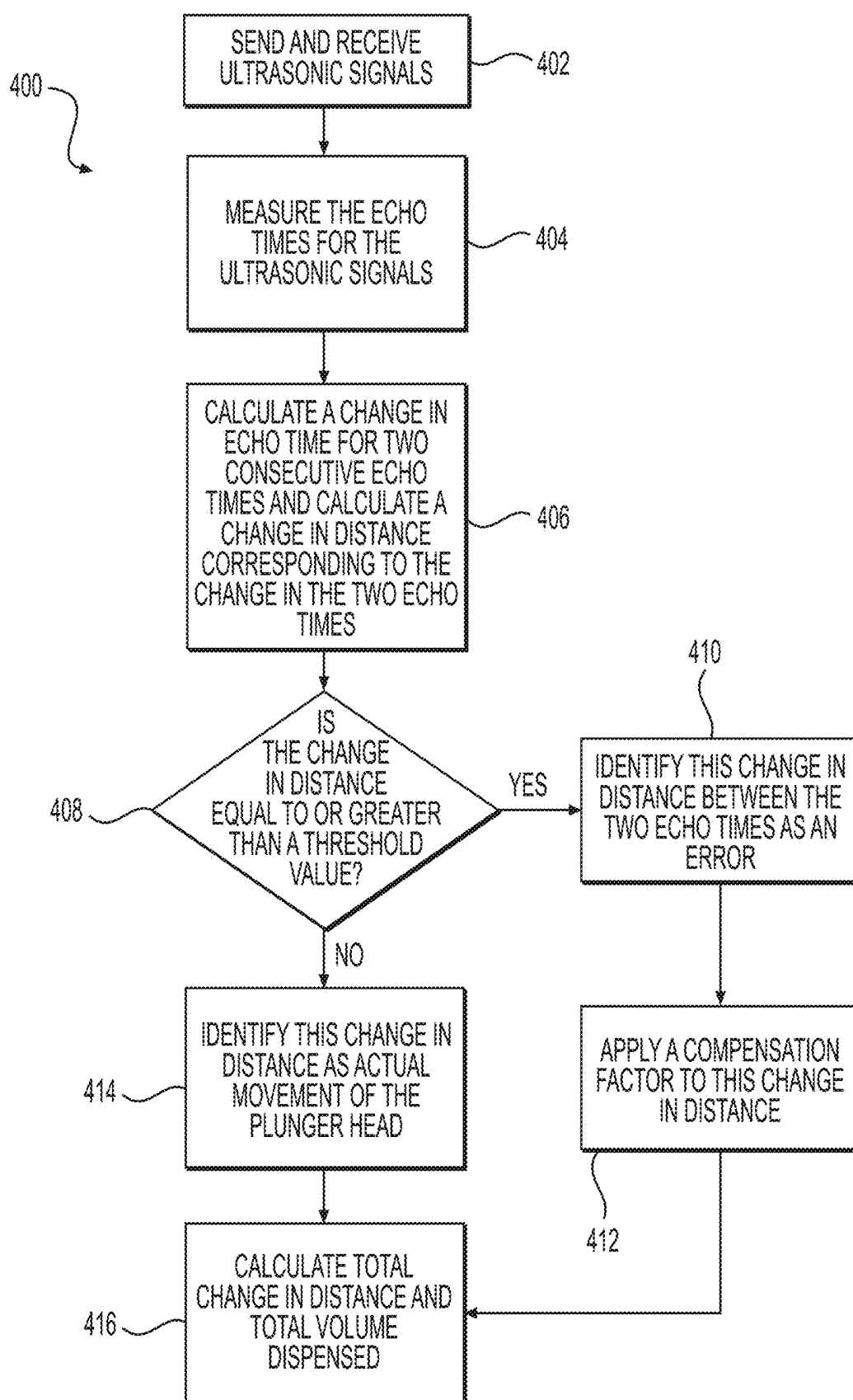


FIG. 3

**FIG. 4**

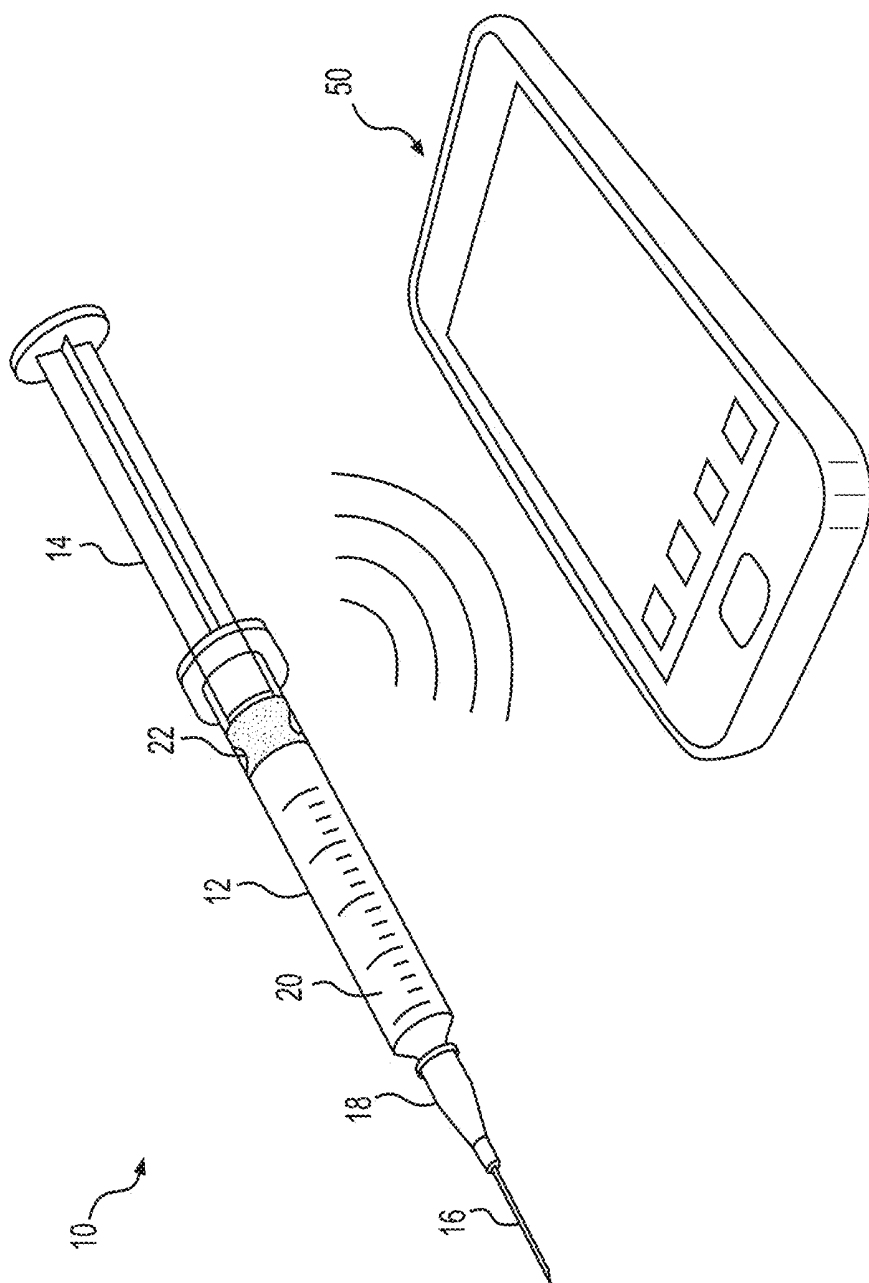
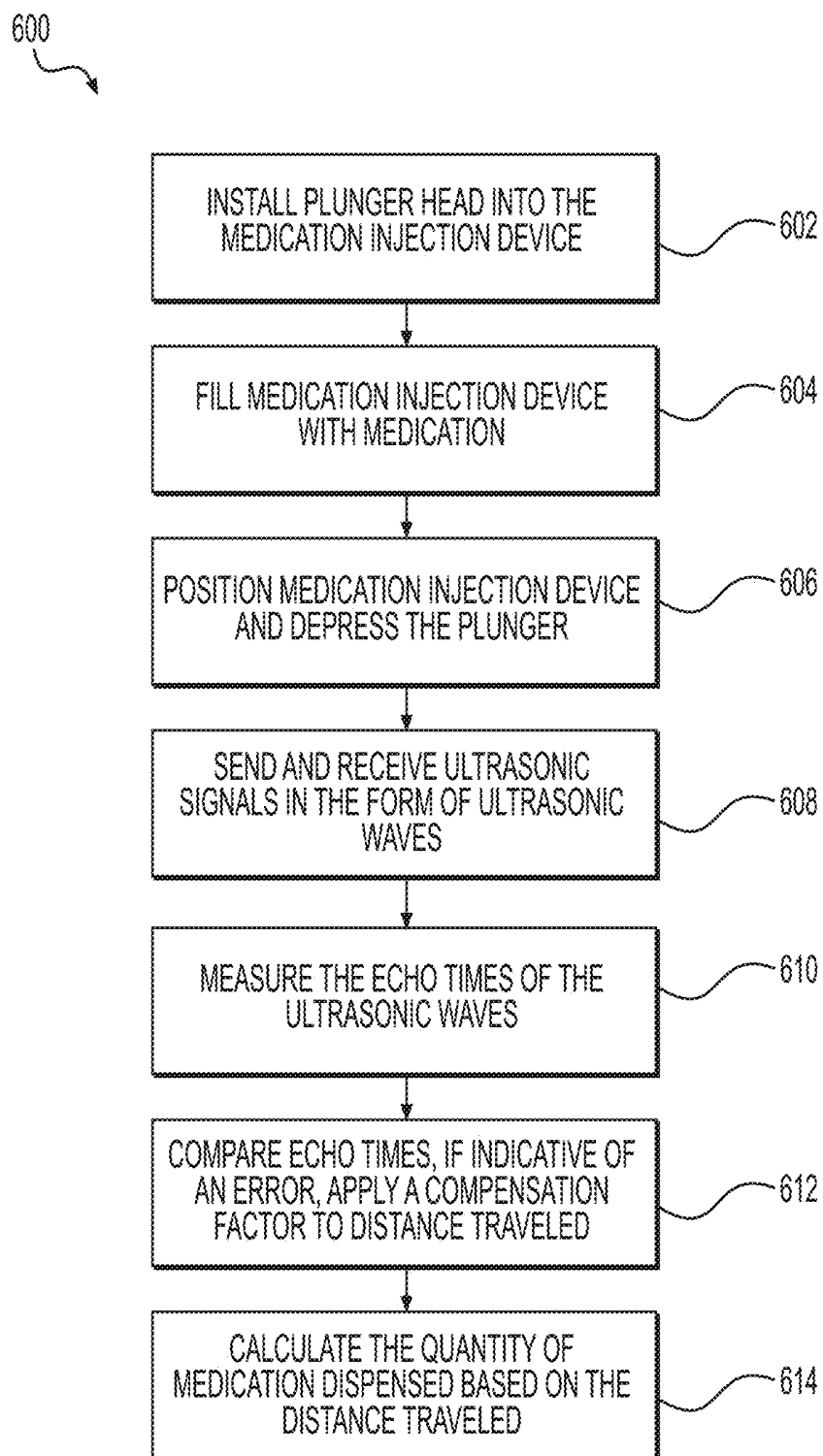


FIG. 5

**FIG. 6**

ULTRASOUND TRACKING OF MEDICATION DELIVERY BY MEDICATION INJECTION DEVICES

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a divisional of U.S. application Ser. No. 15/790,932, filed on Oct. 23, 2017, which claims priority to U.S. Provisional Application No. 62/411,926 filed Oct. 24 2016. Both of these applications are hereby incorporated by reference.

TECHNICAL FIELD

[0002] The present disclosure relates generally to the field of tracking of medication delivery using medication injection device, and more particularly, apparatuses and methods of improved ultrasound tracking of medication delivery by medication injection devices.

BACKGROUND DESCRIPTION

[0003] Measuring the quantity and recording the timing of a drug's administration is an integral part of many disease treatments. For many treatments, to achieve the best therapeutic effect, specific quantities of a drug may need to be injected specific times of day. For example, individuals suffering from diabetes may be required to inject themselves regularly throughout the day in response to measurements of their blood glucose. The frequency and volume of insulin injections must be carefully tracked and controlled to keep the patient's blood glucose level within a healthy range. Currently, there are a limited number of methods or devices for automatically tracking the drug administration without requiring the user to manually measure and record the volume, date, and time. A variety of glucose injection syringes/pens have been developed, but there is much room for significant advancement in the technology in order to reduce the size, lower the cost, and enhance its functionality, accuracy, and reliability thus making it a more viable long-term solution. For example, current insulin pens are often disposable, but do not include dosage tracking. A smaller portion of the market is composed of reusable pens which are more expensive, and still do not include good dosage-tracking capabilities.

SUMMARY

[0004] The present disclosure is directed to systems and methods of drug administration using a syringe with a smart plunger head.

[0005] In one aspect, the present disclosure is directed to a plunger head for a medication injection device. The plunger head may include an elastomer housing that fits within a barrel of the medication injection device. The plunger head may also include an ultrasonic transducer that sends and receives ultrasonic signals in the form of ultrasonic waves, an antenna, a microcontroller that interfaces with the ultrasonic transducer and the antenna, and a power source that powers the microcontroller and the ultrasonic transducer. The ultrasonic transducer, the antenna, the microcontroller, and the power source may be at least partially encapsulated in the elastomer housing. The microcontroller may be programmed with instructions to measure echo times of the ultrasonic waves and compare consecutive echo times and if a change in distance corresponding to a

change in the consecutive echo times is indicative of an error, the microcontroller may apply a compensation factor to the change in distance. The microcontroller may also be programmed with instructions to calculate a volume of medication dispensed from the barrel based on the change in distance of the plunger head.

[0006] In another aspect, the present disclosure is directed to a method of tracking administering of a medication delivered by a medication injection device. The method may include depressing a plunger of the medication injection device and sending and receiving ultrasonic signals in the form of ultrasonic waves from a plunger head installed within a barrel of the syringe. The method may also include measuring the echo times of the ultrasonic waves, wherein the echo time is the time it takes for an ultrasonic wave to travel through the medication to an end of a barrel, reflect, and return to the plunger head. The method may further include comparing consecutive echo times and if a change in distance corresponding to a change in the consecutive echo times is indicative of an error, the microcontroller applies a compensation factor to the change in distance. The method may also include calculating a volume of the medication dispensed based on a distance the plunger head travels.

BRIEF DESCRIPTION OF DRAWINGS

[0007] FIG. 1 is a perspective view of a medication injection device, which includes a plunger head according to an exemplary embodiment.

[0008] FIG. 2 is a schematic of the plunger head of FIG. 1.

[0009] FIG. 3 is a schematic illustrating the behavior of ultrasonic signals transmitted by the plunger head of FIG. 2.

[0010] FIG. 4 is a flow chart illustrating a method of error checking and correcting performed by the plunger head of FIG. 2.

[0011] FIG. 5 is a perspective view of the medication injection device of FIG. 1 communicating with a remote device, according to an exemplary embodiment.

[0012] FIG. 6 is a flow chart illustrating a method of tracking administering of medication by a medication injection device, according to an exemplary embodiment.

DETAILED DESCRIPTION

[0013] Reference will now be made in detail to embodiments of the present disclosure, examples of which are illustrated in the accompanying drawings. Where possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

[0014] FIG. 1 shows a perspective view of a medication injection device 10 designed for ejecting a fluid. Medication injection device 10 may include a barrel 12, a plunger 14, a needle 16, and a hub 18 connecting needle 16 to barrel 12. Barrel 12 may be configured to contain a fluid, for example, a medication 20 and medication injection device 10 may be configured to dispense medication 20 from needle 16 when plunger 14 is depressed. A standard medication injection device (e.g., a syringe) usually contains a plunger head at the end of the plunger that seals off the open top of the barrel and forces the fluid out the needle when the plunger is depressed. The plunger head for a standard medication injection device is usually a unitary piece of molded plastic or rubber.

[0015] For medication injection device 10 shown in FIG. 1, the standard plunger head has been replaced with a smart

or intelligent plunger head **22** that is configured to measure and register the quantity of medication **20** administered and the date and time of administration. Plunger head **22** may be installed in a standard medication injection device by withdrawing plunger **14** and removing the standard plunger head and installing smart plunger head **22**. In some embodiments, medication injection device **10** may be manufactured and supplied with a smart plunger head **22** preinstalled. Smart plunger head **22** may be referred herein as either smart plunger head **22** or plunger head **22**.

[0016] Plunger head **22** may be sized to correspond with the size of barrel **12**. For example, plunger head **22** may be formed to fit any size medication injection device **10**. For example, plunger head **22** may be sized to fit a 1 ml, 2 ml, 3 ml, 5 ml, 10 ml, 20 ml, 30 ml, or 50 ml medication injection device.

[0017] FIG. 2 shows a schematic of plunger head **22**, according to an exemplary embodiment. Plunger head **22** may include an ultrasonic transducer **24**, a microcontroller **26**, a power source **28**, and an antenna **30** (e.g., for near field communication (NFC), which in some embodiments may be a transceiver (e.g., for BLUETOOTH low energy (BLE) communication). In some embodiments, the components of plunger head **22** may be at least partially encapsulated in an elastomer (e.g., rubber, ethylene propylene (EPM), nitrile rubber (NBR), ethylene propylene diene (EPDM), polybutadiene, and polyisoprene). Ultrasonic transducer **24** may be configured to send and receive ultrasonic signals. Microcontroller **26** may be programmed with instructions to control the overall operation of the plunger head. Antenna **30** may be configured to wirelessly communicate with a remote device (e.g., a smart phone, a glucose monitor, an insulin pump, and a computer) using one or more wireless communication methods. The one or more wireless communication methods may include, for example, radio data transmission, Bluetooth, BLE, NFC, infrared data transmission, electromagnetic induction transmission, and/or other suitable electromagnetic, acoustic, or optical transmission methods. Power source **28** may be configured to power ultrasonic transducer **24**, microcontroller **26**, and Antenna **30**.

[0018] Microcontroller **26** may include one or more processors, including for example, a central processing unit (CPU). The processors may include any suitable type of commercially available processor or may be a custom design. Microcontroller **26** may include additional components, for example, non-volatile memory (e.g., a flash memory), volatile memory (e.g., a random access memory (RAM)), and other like components, configured to store information and/or programmed instructions).

[0019] In some embodiments, plunger head **22** may also include a crystal oscillator **32** configured to keep accurate time so that the date and time of each injection may be accurately recorded and stored in memory of microcontroller **26**. Crystal oscillator may be, for example, a 32 KHZ crystal oscillator. In some embodiments, crystal oscillator **32** may be internal to microcontroller **26**. In some embodiments, an external high speed RC oscillator (e.g., 10 MHZ) may be used to provide sufficient time accuracy to measure the echo times.

[0020] Power source **28** may be any suitable power source. For example, power source **28** may be a battery, a capacitor, or the like. In some embodiments, power source **28** may be rechargeable via wireless energy transmission,

for example, inductive coupling, resonant inductive coupling, radio frequency (RF) link, or the like. In some embodiments, power source **28** may be a non-rechargeable battery that is configured to last the operational life of plunger head **22**, for which the operational life may be about 1 year, about 2 years, about 3 years, or more. For example, in some embodiments, power source **28** may be a watch battery. In some embodiments, where plunger head **22** is a passive device as described herein, power source **28** may be eliminated.

[0021] Antenna **30** may be used to communicate with a variety of remote devices (e.g., smart phones, glucose monitors, insulin pumps, computers, etc.). Plunger head **22** may transmit the information via any suitable wireless communication method. For example, in some embodiments, plunger head **22** may utilize radio data transmission, BLUETOOTH or BLE, NFC, infrared data transmission or other suitable method. In some embodiments, information may also be wirelessly transmitted from a remote device to plunger head **22** via antenna **30**. For example, the date and time may be set by writing to microcontroller **26** via the wireless communication.

[0022] As shown in FIG. 2, in some embodiments, plunger head **22** may also include force sensor **34**. Force sensor **34** may be configured to detect when a force is applied to plunger head **22** via plunger **14**, which for example may indicate that dispensing of medication is being initiated. Force sensor **34** may be, for example, a simple spring-loaded switch that is molded into the plunger head **22**. In some embodiments, ultrasonic transducer **24** may be configured to function as a force sensor thereby eliminating the need for a separate force sensor **34**. For example, ultrasonic transducer **24** may have a piezoelectric element that may detect the dynamic changes in pressure when a user depresses the plunger **14**.

[0023] In some embodiments, as shown in FIG. 2, plunger head **22** may include a temperature sensor **36**. Temperature sensor **36** may be configured to measure the temperature of medication **20**. Microcontroller **26** may be configured to use the temperature of medication **20** to compensate for variations in the temperature that would affect the speed of sound within the medication, thus improving the accuracy of the distance and volume calculations. In some embodiments, microcontroller **26** may also use temperature sensor **36** to monitor the temperature of medication **20** to ensure that the temperature of medication **20** stays within an acceptable range. The efficacy of some medications is affected by temperature.

[0024] Ultrasonic transducer **24** may be an actuator, piezoelectric element, or speaker-like voice coil configured to generate and send a pressure wave or ultrasonic signals in the form of ultrasonic waves. In some embodiments, ultrasonic transducer may be a resonant thickness-mode transducer. Ultrasonic transducer **24** may be sized to be slightly smaller than the inner diameter of barrel **12**. As shown in FIG. 3, ultrasonic transducer **24** may be configured to generate ultrasonic signals **25** (e.g., radiated ultrasonic sound energy waves) and send the ultrasonic signals **25** down barrel **12** toward hub **18** and needle **16**. The frequency of the ultrasonic signals **25** may be determined by the thickness of ultrasonic transducer **24**. By vary the thickness of ultrasonic transducer **24** the frequency of the ultrasonic signals **25** may be varied. For example, the frequency range for the ultrasonic signals may range from about 2 MHz to

about 4 MHz, about 2 MHz to about 3 MHz, or about 3 MHz to about 4 MHz. In some embodiments, the static capacitance of the ultrasonic transducer **24** may also be varied. For example, in some embodiments the static capacitance may be about 900 pF, about 800 pF, about 700 pF, or less. According to one illustrative embodiment, for an ultrasonic transducer **24** having a static capacitance of about 900 pF, one ultrasonic pulse of the ultrasonic signals **25** may be generated by supplying about 3V to ultrasonic transducer **24**, which translates to about 4 nanoJoules (nJ) of energy per pulse. The energy per pulse may be reduced, for example, by reducing the static capacitance of ultrasonic transducer **24**.

[0025] The ultrasonic signals **25** can travel through medication **20** along the length of barrel **12** and bounce or reflect off an end **27** of barrel **12** and travel back through medication **20** to plunger head **22**. The reflected ultrasonic signals or ultrasonic echo can be received and detected by ultrasonic transducer **24**. A velocity V of sound in medication **20** may be a known value and thus a distance D can be calculated, according to the formula: $D=Vt/2$, very accurately where time t is the time it takes for an ultrasonic signal to travel down and back (i.e., $2D$) from ultrasonic transducer **24**. In other words, distance D can be calculated based on the measured time between when an ultrasonic signal **25** is transmitted by ultrasonic transducer **24** and the ultrasonic echo is detected by ultrasonic transducer **24**, and that time is referred to herein as the echo time. As plunger head **22** is moved down barrel **12**, distance D will decrease along with the echo time and the volume of medication in barrel **12**. And by knowing the radius r of barrel **12** then the volume V of medication **20** dispensed may be calculated based on the change in distance D according to the formula: $V=\pi r^2 D$. A suitable sampling rate of the ultrasonic signals can be selected so that the displacement of plunger head **22** can be accurately tracked regardless of the speed at which plunger **14** may be depressed. For example, in some embodiments, a suitable sampling rate may be about 100 ms, about 80 ms, about 60 ms, about 40 ms, about 20 ms, about 10 ms, or less than about 10 ms. In other embodiments, the sampling rate may be slower to conserve battery life. For example, the sampling rate may be about 1 second.

[0026] As shown in FIG. 3, in some embodiments, a porous membrane **29** may be placed within barrel **12** at end **27**. Porous membrane **29** may be designed to allow medication **20** to pass through while providing a surface with good reflective properties for the ultrasonic signals **25** to reflect back towards ultrasonic transducer **24**. Utilizing porous membrane **29** may improve the accuracy of the echo detection and thereby the distance and volume calculations. It is contemplated that other materials may be used besides a porous membrane. It is also contemplated that the geometry of barrel **12** at end **27** may dictate whether a porous membrane is needed. For example, in some embodiments the geometry of end **27** may be designed to produce the desired reflective properties avoiding the need to employ porous membrane **29**.

[0027] Microcontroller **26** may be programmed with instructions to control the operation of ultrasonic transducer **24**. Microcontroller **26** may be programmed with instructions to calculate data representative of the quantity of medication **20** dispensed. For example, in some embodiments, microcontroller **26** may be programmed to detect and record the echo times of the ultrasonic signals **25**. Based on the echo times, microcontroller **26** may calculate distance D

and volume V . Microcontroller **26** may also produce an echo time profile of the distance between ultrasonic transducer **24** (i.e., plunger head **22**) and end **27**. Based on the echo time profile of the distance, microcontroller **26** may be able to identify a first distance D_1 or starting position (e.g., before medication **20** is dispensed), which may correspond with barrel **12** being filled and a second distance D_2 or ending position (e.g., after medication **20** is dispensed), which may correspond with barrel **12** being empty. Microcontroller **26** may then calculate the change in distance between D_1 and D_2 and based on this total change in distance may calculate the total volume (i.e., amount or quantity) of medication **20** dispensed. In some embodiments, incremental changes in distance D may be calculated, for example, between each ultrasonic signal **25**, as plunger head **22** travels down barrel **12**, which may then allow for incremental changes in volume to be calculated. Therefore, the total distance traveled by plunger head **22** and total volume dispensed may be calculated in one or more ways. For example, the total distance traveled and total volume dispensed may be calculated based on the starting position and the ending position or the total distance and total volume may be calculated by totaling the incremental measurements.

[0028] Ultrasonic transducer **24** and/or microcontroller **26** may be programmed with instructions to perform various forms of signal conditioning to improve the accuracy by which the echo time of the reflected ultrasonic signals **25** are detected and measured. For example, as plunger head **22** approaches end **27** of barrel **12**, when dispensing medication **20**, measuring the echo time can become increasingly difficult as the echo time becomes shorter and shorter and are more susceptible to destructive (e.g., multi-path) wave interference. Ordinarily, a front edge of each reflected wave of the ultrasonic signal **25** may be used to measure the echo time. But, as plunger head **22** gets closer to end **27** destructive interference may cause the front edge of the reflected waves to become distorted (e.g., change shape or jump). When the front edge of the reflected wave jumps, this change may not be indicative of actual movement of plunger head **22**, but may instead be caused by destructive (e.g., multi-wave) interference. Therefore, if this movement is incorrectly identified as movement of plunger head **22**, it can lead to inaccurate measurement of the volume of medication **20** remaining in barrel **12** as well as the volume of medication **20** dispensed.

[0029] The front edges of the reflected waves may jump forward (e.g., early or back (e.g., late). When the front edges of the reflected waves jump, the jump will typically be equal to a wavelength of ultrasonic signal **25**. In some embodiments, the jump may be equal to an integer multiple of the wavelength (e.g., 2 wavelengths, 3 wavelengths, or more wavelengths). Therefore, in order to improve the accuracy of the echo time measurement, particularly when plunger head **22** approaches end **27**, microcontroller **26** may be programmed with instructions to identify and compensate for these jumps. It has been observed that it is about the final 20% of the travel distance of plunger head **22** that is increasingly affected by the destructive interference. Therefore, in some embodiments, microcontroller **26** may be programmed to start executing the instructions that identify and compensate for these jumps when plunger head **22** is down to about the last 20% of the travel distance. In other embodiments, the instructions that identify and compensate for these jumps may always be executing.

[0030] In order to identify and compensate for these jumps, microcontroller 26 may be programmed to measure and track the echo time of each wave of ultrasonic signal 25. Microcontroller 26 may then compare the echo time of consecutive echo times to calculate a change in echo times between the consecutive echo times. In some embodiments, microcontroller 26 may calculate a moving average of echo times (e.g., using a low-pass filter) and compare the consecutive measurements of the moving average. And, if the calculated change in distance corresponding to the change in the echo times is above a threshold value, then microcontroller 26 can identify the latest echo time as an error. In some embodiments, the threshold value may be equal to the wavelength of ultrasonic signals 25. When microcontroller 26 identifies an echo time as an error, microcontroller can apply (e.g., subtract or add) a compensation factor, depending on whether the jump was early or late, to the calculated change in distance to correct the error. For example, when the threshold value is one wavelength, the compensation factor may also be equal to one wavelength. In some embodiments, once the compensation factor is applied, microcontroller 26 may use the corrected change in distance when calculating a total distance traveled by plunger head 22 and total volume of medication dispensed.

[0031] When microcontroller 26 compares an echo time to the previous echo time and the change in distance corresponding to the change in echo times is less than the threshold value (e.g., one wavelength of ultrasonic signal 25), microcontroller 26 may be programmed to recognize this change in distance as actual movement of plunger head 22, which microcontroller 26 may use to calculate the total distance traveled by plunger head 22 and total volume of medication dispensed.

[0032] Example 1, described below, provides some values and ranges for a functional operation of medication injection device 10 and plunger head 22, according to an exemplary embodiment.

EXAMPLE 1

[0033] According to Example 1, barrel 12 of medication injection device 10 is sized to hold a volume of about 3 ml of medication 20 and configured to allow plunger head 22 to travel a distance D of about 42.5 mm. Microcontroller 26 is programmed to operate at sampling rate of 20 ms. Ultrasonic transducer 24 is constructed to generate the ultrasonic signal 25 at a frequency of about 2.6 MHz. The wavelength of the ultrasonic signals 25 will depend on the frequency and fluid (i.e., medication 20), but for the purposes of Example 1, the medication is assumed to be water. Thus, at a frequency of about 2.6 MHz the ultrasonic signals 25 will have a wavelength of about 0.57 mm. When plunger head 22 is positioned at its starting point, which corresponds to barrel 12 being filled with 3 ml of medication 20 (i.e., water), an echo time for the ultrasonic signals 25 is about 60 microseconds. As plunger 14 is depressed causing plunger head 22 to travel down barrel 12, the echo time decreases. When plunger head 22 reaches the end of barrel 12, the echo time is about 7 microseconds.

[0034] FIG. 4 illustrates an exemplary method 400 performed by microcontroller 26 as plunger head 22 travels down barrel 12, which may correspond to Example 1. Exemplary method 400 can identify sampling errors caused by destructive interference and corrects the errors. As plunger head 22 travels down barrel 12, the method may

begin by ultrasonic transducer 24 sending and receiving ultrasonic signals 25 (Step 402). At step 404, microcontroller 26 may measure the echo times for the ultrasonic signals 25. In some embodiments, microcontroller 26 may be sending ultrasonic signals at a sampling rate of 20 ms, and after each sampling, microcontroller 26 may be programmed to calculate a change in echo time for two consecutive echo times and calculate a change in distance corresponding to the change in the two echo times (Step 406). If the calculated change in distance between the consecutive echo times is above a threshold value (e.g., a wavelength of the ultrasonic signals 25) (Step 408: Yes), microcontroller 26 may proceed to step 410. At step 410, microcontroller can identify this change in distance between the two echo times as an error. When microcontroller 26 identifies an error, microcontroller 26 can apply (e.g., subtract or add) a compensation factor to the change in distance associated with that sampling, depending on whether the jump was early or late, to correct for the error (Step 412). For some embodiments, the compensation factor may be equal to one wavelength of electrical signals 25. Returning to step 408, if the calculated change in distance between the consecutive echo times is below a threshold value (Step 408: No), microcontroller 26 may proceed to step 414. At step 414, microcontroller 26 may identify this change in distance as actual movement of plunger head 22. At step 416, microcontroller 26 may calculate the total change in distance of plunger head 22 and total dispensed volume of medication 20.

[0035] Referring now to FIG. 5, plunger head 22 may transmit the amount of medication 20 dispensed along with the time and date it was dispensed to a remote device 50 (e.g., a smart phone, a glucose monitor, an insulin pump, and a computer) via one or more of the wireless communication methods. Plunger head 22 may have a unique identifier so remote device 50 may be able to identify and process the information received properly. Plunger head 22 may transmit this information to remote device 50 immediately or shortly after the medication is administered or plunger head 22 may store the information until remote device 50 is within range. The information may be stored, for example, in memory of microcontroller 26. In some embodiments, plunger head 22 may wait to initiate transmitting of the information until initiated by remote device 50. For example, a user may initiate information retrieval on remote device 50. In some embodiments, remote device 50 may transmit the information to a caregiver (e.g., a doctor) or upload the information to the cloud so it may be saved to the patient's medical history and may be accessed by the caregiver. The ability of a caregiver or a patient to access and review the dose history may improve treatment. For example, the ability of a caregiver to review a diabetic insulin injection history and continuous glucose measurement data may enable the caregiver to adjust the prescribed treatment to improve the therapeutic effect, for example, by better stabilizing the patient's glucose levels.

[0036] In some embodiments, microcontroller 26 may be configured to simply detect the echo times of the ultrasonic signals 25 and transmit the echo times to remote device 50 and the remote device may perform all the calculations and signal conditioning operations in order to calculate the volume of medication 20 dispensed.

[0037] Plunger head 22 described herein may be utilized for a variety of methods for tracking administering of a medication to a patient delivered by a medication injection

device. Various methods of utilizing plunger head 22 will now be explained with reference to FIG. 7. In some embodiments, the methods as described herein may be performed by a caregiver (e.g., a doctor or nurse) in a hospital or other inpatient setting. In some embodiments, the methods as described herein may be performed by a caregiver (e.g., a doctor, nurse, or parent) at home or outside a hospital. In some embodiments, the methods as described herein may be performed by the patient. It is contemplated that the methods described herein may be performed in other settings by other individuals.

[0038] Plunger head 22 may be utilized for a method 600 of tracking administering of a medication to a patient delivered by a medication injection device, according to an exemplary embodiment, as shown in FIG. 6. Method 600 may incorporate method 400, as described herein, as a subpart of method 600.

[0039] In some embodiments, at step 602, method 100 may begin by installing plunger head 22 into barrel 12 of medication injection device 10 (e.g., a disposable syringe). In some embodiments, medication injection device 10 may be supplied with plunger head 22 already installed, thereby eliminating this step.

[0040] Next, at step 604, barrel 12 of medication injection device 10 may be filled with medication 20. Barrel 12 may be completely filled or only partially with medication 20. In some embodiments, medication injection device 10 may be supplied prefilled with medication 20, thereby eliminating this step. In some embodiments, plunger head 22 may be configured to “wake up” in response to a force applied during the filling, which may be detected by force sensor 34.

[0041] Once filled, at step 606, medication injection device 10 may then be positioned for administration. For example, needle 16 may be inserted into the skin of the patient or into a drug delivery port connected to the patient. Once in position, plunger 14 of medication injection device 10 may be depressed, which forces the medication 20 out the needle 16 as plunger head 22 is forced down barrel 12.

[0042] While plunger 14 is being depressed, plunger head 22 may send and receive ultrasonic signals 25 in the form of ultrasonic waves via ultrasonic transducer 24, at step 608. Step 608 may correspond to step 402 of method 400. Plunger head 22 may be configured to send and receive ultrasonic signals 25 the duration of the time, that plunger 14 is being depressed. Plunger head 22 may measure the echo times of the ultrasonic waves, for step 610. Step 610 may correspond to step 404 of method 400.

[0043] At step 612, plunger head 22 may compare echo times, and if a change in distance calculated based on a change in the echo times is indicative of an error, then plunger head 22 may apply a compensation factor to the change in distance. Step 612 may correspond to steps 406, 408, 410, and 412 of method 400. At step 614, the quantity of medication 20 dispensed may be calculated based on the calculated distance the plunger head 22 traveled. Step 614 may correspond to step 416 of method 400.

[0044] For some embodiments of method 600, the change in distance calculated based on a change in the echo times may be indicative of an error when the change in distance is equal to about one wavelength of the ultrasonic waves. For some embodiments of method 600, at step 612, plunger head 22 may recognize the change in distance as an actual movement of the plunger head when the change in distance

calculated based on a change in the echo times is less than one wavelength of the ultrasonic waves.

[0045] In some embodiments, method 600 may also include transmitting the quantity of the medication dispensed and the time and date the quantity was dispensed to a remote device. In some embodiments, method 600 may also include uploading the quantity of the medication dispensed and the time and date the quantity was dispensed to the cloud. In some embodiments, method 600 may also include sending the quantity of the medication dispensed and the time and date the quantity was dispensed to a caregiver.

[0046] The foregoing description has been presented for purposes of illustration. It is not exhaustive and is not limited to precise forms or embodiments disclosed. Modifications, adaptations, and other applications of the embodiments will be apparent from consideration of the specification and practice of the disclosed embodiments. For example, the described embodiments of plunger head 22 may be adapted for use with a variety of medication injection devices, including for example, syringes, auto-injectors, auto-syringes, injector pens (e.g., insulin pens), or other drug or medication injection devices. The described embodiments of plunger head 22 may be also adapted for use with a variety of other injection or dispensing devices, which may be medical or non-medical related. For example, plunger head 22 may be used in non-medical fluid dispensing applications where the measurement and tracking of the volume of fluid being dispensed is of interest.

[0047] Moreover, while illustrative embodiments have been described herein, the scope includes any and all embodiments having equivalent elements, modifications, omissions, combinations (e.g., of aspects across various embodiments), adaptations and/or alterations based on the present disclosure. The elements in the claims are to be interpreted broadly based on the language employed in the claims and not limited to examples described in the present specification or during the prosecution of the application, which examples are to be construed as nonexclusive. Further, the steps of the disclosed methods can be modified in any manner, including reordering steps and/or inserting or deleting steps.

[0048] The features and advantages of the disclosure are apparent from the detailed specification, and thus, it is intended that the appended claims cover all systems and methods falling within the true spirit and scope of the disclosure. As used herein, the indefinite articles “a” and “an” mean “one or more.” Similarly, the use of a plural term does not necessarily denote a plurality unless it is unambiguous in the given context. Words such as “and” or “or” mean “and/or” unless specifically directed otherwise. Further, since numerous modifications and variations will readily occur from studying the present disclosure, it is not desired to limit the disclosure to the exact construction and operation illustrated and described, and accordingly, all suitable modifications and equivalents may be resorted to, falling within the scope of the disclosure.

[0049] Computer programs, program modules, and code based on the written description of this specification, such as those used by the microcontrollers, are readily within the purview of a software developer. The computer programs, program modules, or code can be created using a variety of programming techniques. For example, they can be designed in or by means of Java, C, C++, assembly language, or any

such programming languages. One or more of such programs, modules, or code can be integrated into a device system or existing communications software. The programs, modules, or code can also be implemented or replicated as firmware or circuit logic.

[0050] Other embodiments will be apparent from consideration of the specification and practice of the embodiments disclosed herein. It is intended that the specification and examples be considered as example only, with a true scope and spirit of the disclosed embodiments being indicated by the following claims.

1. A machine-accessible storage medium providing instructions that, when executed by a medication injection device, will cause the medication injection device to perform operations comprising:

- sending ultrasonic signals as ultrasonic waves from a plunger head into a barrel of the medication injection device;
- receiving reflections of the ultrasonic waves from the barrel;
- measuring echo times of ultrasonic waves;
- comparing consecutive echo times of the ultrasonic waves to determine a change in distance travelled by the plunger head;
- assessing whether the change in distance is deemed to be indicative of an error;
- applying a compensation factor to the change in distance when the change in distance is deemed to be indicative of the error; and
- calculating a volume of medication dispensed from the barrel based on the change in distance of the plunger head, as compensated by the compensation factor when the change in distance is deemed to be indicative of the error.

2. The machine-accessible storage medium of claim 1, wherein assessing whether the change in distance is deemed to be indicative of the error comprises:

- identifying when the change in distance is greater than or equal to about one wavelength of the ultrasonic waves.

3. The machine-accessible storage medium of claim 2, wherein the compensation factor is equal to about one wavelength of the ultrasonic waves.

4. The machine-accessible storage medium of claim 1, further providing instructions that, when executed by the medication injection device, will cause the medication injection device to perform further operations, comprising:

- determining that the change in distance is not indicative of the error when the change in distance is less than one wavelength of the ultrasonic waves.

5. The machine-accessible storage medium of claim 1, wherein the ultrasonic signals have a frequency between about 2 Mhz and about 3 Mhz.

6. The machine-accessible storage medium of claim 1, further providing instructions that, when executed by the medication injection device, will cause the medication injection device to perform further operations, comprising:

- starting to assess whether the change in distance is deemed to be indicative of the error only after the plunger head reaches a last 20% of a total available travel distance of the plunger head within the barrel.

7. The machine-accessible storage medium of claim 1, further providing instructions that, when executed by the medication injection device, will cause the medication injection device to perform further operations, comprising:

transmitting data indicative of the volume of medication dispensed from the barrel to a remote device via an antenna.

8. The machine-accessible storage medium of claim 7, further providing instructions that, when executed by the medication injection device, will cause the medication injection device to perform further operations, comprising:

- registering a date and time the volume of medication is dispensed; and
- transmitting the date and time to the remote device along with the data indicative of the volume of medication dispensed.

9. The machine-accessible storage medium of claim 1, further providing instructions that, when executed by the medication injection device, will cause the medication injection device to perform further operations, comprising:

- measure a temperature of the volume of medication with a temperature sensor; and
- compensating for changes in the temperature of the volume of medication when calculating the volume of medication dispensed.

10. The machine-accessible storage medium of claim 1, wherein the medication injection device is at least one of a disposable syringe, an auto-injector, or an insulin pen.

11. A method of tracking administration of a medication delivered by a medication injection device, the method comprises:

- depressing a plunger of the medication injection device;
- sending and receiving ultrasonic signals in the form of ultrasonic waves from a plunger head installed within a barrel of the syringe;
- measuring the echo times of the ultrasonic waves, wherein the echo time is the time it takes for an ultrasonic wave to travel through the medication to an end of a barrel, reflect, and return to the plunger head;
- comparing consecutive echo times and if a change in distance corresponding to a change in the consecutive echo times is indicative of an error, the microcontroller applies a compensation factor to the change in distance; and

calculating a volume of the medication dispensed based on a distance the plunger head travels.

12. The method of claim 11, wherein the change in distance corresponding to the change in the consecutive echo times is indicative of an error when the change in distance is greater than or equal to about one wavelength of the ultrasonic waves.

13. The method of claim 12, wherein the compensation factor is equal to about a wavelength of the ultrasonic waves.

14. The method of claim 11, further comprising identifying the change in distance corresponding to the change in the consecutive echo times as actual movement of the plunger head if the change in distance is less than one wavelength of the ultrasonic waves.

15. The method of claim 11, further comprising selectively transmitting wirelessly the volume of the medication dispensed to a remote device.

17. The method of claim 16, further comprising registering the date and time the medication is dispensed and transmitting the date and time to the remote device along with the volume of medication dispensed.

18. The method of claim 11, wherein the medication injection device is a standard disposable syringe, and the

method further comprises installing the plunger head into the syringe prior to filling the barrel of the syringe with a medication.

10. The method of claim **11**, wherein the medication injection device is at least one of a disposable syringe, an auto-injector, or insulin pen.

20. The method of claim **11**, further comprising starting the comparing of consecutive echo times when the plunger head reaches the last 20% of a total available travel distance.

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专利名称(译)	通过药物注射装置对药物输送进行超声跟踪		
公开(公告)号	US20190374723A1	公开(公告)日	2019-12-12
申请号	US16/534715	申请日	2019-08-07
申请(专利权)人(译)	实实在在的生命科学LLC		
当前申请(专利权)人(译)	实实在在的生命科学LLC		
[标]发明人	KRASNOW BENJAMIN DAVID		
发明人	KRASNOW, BENJAMIN DAVID		
IPC分类号	A61M5/315 A61M5/142 A61B5/00		
CPC分类号	A61B5/0026 A61B5/002 A61M5/142 A61B5/4839 A61M5/31568 A61M2205/33 A61B5/4848 A61M5/31511 A61M2205/3306 A61M2205/332 A61M2205/3368 A61M2205/3375 A61M2205/3561 A61M2205/3584 A61M2205/50 A61M2205/8206		
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摘要(译)

药物注射装置包括柱塞头，该柱塞头具有装配在筒体内的弹性体壳体。柱塞头包括发送和接收超声波形式的超声信号的超声换能器，天线，与超声换能器和天线接口的微控制器以及为微控制器和超声换能器供电的电源。超声换能器，天线，微控制器和电源可以至少部分地封装在弹性体壳体中。微控制器可以被编程为测量超声波的回波时间，比较连续的回波时间，并施加补偿因子。微控制器也可以被编程为计算从针筒分配的药物的体积。

