(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
16 July 2009 (16.07.2009)

PCT

(10) International Publication Number
WO 2009/089213 A2

(51) International Patent Classification:
A61M 5/14 (2006.01)

(21) International Application Number:
PCT/US2009/030210

(22) International Filing Date: 6 January 2009 (06.01.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
11/971,048 8 January 2008 (08.01.2008) US

(71) Applicants *(for all designated States except US)*: **BAXTER INTERNATIONAL INC.** [US/US]; One Baxter Parkway, Deerfield, Illinois 60015-4633 (US). **BAXTER HEALTHCARE S.A.** [CH/CH]; Hertistrasse 2, CH-8304 Wallisellen, Zurich (CH).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **DELCASTILLO, Jorge** [US/US]; 518 Pinehurst Drive, Des Plaines, Illinois 60016 (US). **YARDIMCI, Atif** [TR/US]; 241 Coventry, Vernon Hills, Illinois 60061 (US).

(74) Agent: **FOLEY, Austin**; Baxter International Inc., One Baxter Parkway, Deerfield, Illinois 60015-4633 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

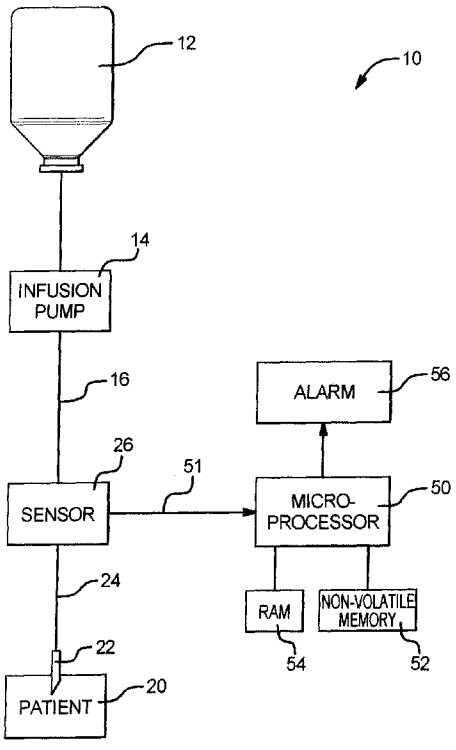
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK,

[Continued on next page]

(54) Title: 'SYSTEM AND METHOD FOR DETECTING OCCLUSION USING FLOW SENSOR OUTPUT'

(57) Abstract: A method and system for detecting an inclusion within an infusion system. The method includes monitoring an output signal of a flowrate sensor as fluid flows through an infusion system. The output signal is then converted with a noise reduction filter to obtain a filtered output signal. The filtered output signal is compared to a threshold value and an alarm is activated if the filtered output signal falls below a desired threshold, thereby indicating an occlusion within the infusion system.

FIG. 1



WO 2009/089213 A2

MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

— *without international search report and to be republished upon receipt of that report*

"SYSTEM AND METHOD FOR DETECTING OCCLUSION USING FLOW SENSOR OUTPUT"

BACKGROUND

[0001] The present disclosure generally relates to methods and devices for detecting abnormal fluid flow through an infusion system. In particular, the present disclosure is related to devices and methods for detecting occlusions within an infusion system.

[0002] Liquid medicaments and other complex medical and therapeutic fluids are often administered to patients through infusion systems. A typical infusion system includes a fluid supply, an infusion flow control device and a fluid pathway. The infusion pathway typically includes one or more sections of fluid lines made of flexible tubing that define a fluid flow path from the fluid supply to a device that administers the fluid to the patient, such as a cannula, needle or catheter. During operation of the infusion system, the infusion control device pushes or forces liquid from the fluid source through the fluid pathway and the administering device into the patient.

[0003] One of the problems that can arise during infusion therapy is an occlusion or blockage which completely blocks or severely limits the flow of fluid through the infusions system. Occlusions are undesirable because they can impair the therapeutic effect of a medication being infused. For example, in some infusion therapy applications the liquid medicament is required to be delivered at a specific fluid flowrate for the medicament to be therapeutically effective. In these instances, an undetected occlusion, causing a decrease in flowrate, can diminish the therapeutic effect of the infusion therapy.

[0004] Additionally, in any infusion therapy application, an undetected occlusion can cause unnecessary delays in the infusion procedure. For instance, if an occlusion is undetected for a relatively long period of time, the time that passes while the occlusion is undetected increases the time required for the infusion therapy. Thus, in order to avoid complications and unnecessary delays in the infusion therapy, it is beneficial to be able to detect occlusions as soon as possible.

[0005] Because an occlusion causes pressure to build within the fluid lines, one common method of detecting an occlusion within an infusion system includes monitoring the pressure of the fluid lines and activating an alarm when the back pressure exceeds a preset threshold. In such methods, a pressure sensor is placed in communication with a fluid line of the system. When an occlusion occurs in the fluid line, flow within the line is blocked or severely limited. As more fluid is added to the fluid pathway by the flow control device, the pressure within the fluid line increases. When the pressure exceeds a certain threshold, an alarm is activated to inform the patient or operator of the occlusion.

[0006] In infusions therapies where the fluid flowrate is relatively high, an occlusion causes a fairly quick increase of pressure within the fluid line, and the occlusion can be detected by a pressure sensor in a relatively short period of time. However, in infusion therapies where the flowrate is relatively low (for example, between about 0.1 ml/hr and about 10 ml/hr), pressure build-up within the fluid lines due to an occlusion can take a significant amount of time to reach the threshold level required for activating the occlusion alarm. Thus, when pressure of the fluid lines is used to detect occlusions in infusion system having low flowrates, there can be a considerable delay between the actual occurrence of an occlusion and the detection of the occlusion.

SUMMARY

[0007] The present disclosure relates to methods and devices for detecting an occlusion within an infusion system. In one embodiment, the infusion system includes a fluid source, a fluid flow control device, such as a fluid pump, and a fluid pathway. The fluid flow control device forces fluid from the fluid source, through the infusion circuit and into the patient. The infusion system also includes a flowrate sensor disposed along the fluid pathway to detect the flowrate through the infusion system. The flowrate sensor provides an analog output signal that expresses the fluid flowrate. The output signal can be in the form of volts, electric current or ticks of a counter. The flowrate sensor is in communication with a processing device, such as a microprocessor, which receives the output signal from the flowrate sensor. The processing device processes the output signal and compares the output signal to a threshold value to determine if an occlusion is present within the infusion system.

[0008] Use of the above device results in a method for detecting an occlusion within an infusion system. The method includes monitoring an output signal of a flowrate sensor that is disposed along the fluid pathway of an infusion system. The fluid path includes a pulsatile fluid flow flowing therethrough. A noise reduction filter, for example a ten second backward averaging filter, converts the output signal to obtain a filtered output signal. The filtered output signal is then compared to a preset threshold. If the filtered output signal falls below the threshold, an alarm is activated to signal to the user that an occlusion or other abnormal flow characteristic is present in the infusion system. In one embodiment, the desired threshold value is based on a baseline of the output signal, which is acquired or captured as fluid is initially flowed through the system. Optionally, the baseline can be converted to a baseline average by employing an averaging filter. In another embodiment, the threshold value is equal to the baseline average minus the standard deviation.

[0009] In another embodiment of the present disclosure, a method of detecting an occlusion within an infusion system is provided. The method includes monitoring an output signal from a flowrate sensor that is disposed along an infusion fluid pathway having a non-continuous or pulsatile flow of fluid therethrough. A data set that includes the output signal as a function of time is taken over a predetermined period of time. A noise rejection filter, such as a low-pass or high-pass frequency filter, filters the date to eliminate noise, such as patient or operator induced artifacts. Spectral analysis is then preformed on the filtered data set to determine the output signal strength in the frequency domain. The strength of the signal for a range or window of frequency that generally correlates with the frequency of the pulsatile fluid flow through the infusion system is calculated. In one embodiment, the strength of the signal of the frequency range is calculated by integrating the power-spectra in frequency domain for the range of frequency and computing the energy metric. The signal strength of the range can then be compared with an upper threshold value, a lower threshold value or both an upper and lower threshold value. If the signal strength is more than the upper threshold value, this indicates that there is an occlusion down stream of the flowrate sensor, and an alarm is activated indicating the same. If the signal strength is less than the lower threshold, this indicates that there is an

occlusion upstream of the flowrate sensor, and an alarm is activated indicating the same.

[0010] Additional features and advantages are described herein, and will be apparent from, the following Detailed Description and the figures.

BRIEF DESCRIPTION OF THE FIGURES

[0011] FIG. 1 is a schematic illustration of one embodiment of an infusion system of the present disclosure;

[0012] FIG. 2 is a graphical illustration of the output signal of the flowrate sensor versus time;

[0013] FIG. 3 is a flowchart illustrating one embodiment of an algorithm of the present disclosure for detecting an occlusion within an infusion system;

[0014] FIG. 4 is a graphical illustration of the filtered output signal versus time; and

[0015] FIG. 5 is a flowchart illustrating another embodiment of an algorithm of the present disclosure for detecting an occlusion within an infusion system.

DETAILED DESCRIPTION

[0016] Referring now to the drawings and is particular to an infusion system 10 includes a fluid source 12, a fluid flow control device 14 and a fluid pathway 16. Fluid pathway 16 can include flexible tubing or other fluid flow conduits 18 that define a fluid path between fluid source 12 and a patient 20. A fluid administering device 22, such as a needle, cannula or catheter, is connected to the distal end 24 of fluid pathway 16 to administer fluid to the patient 20. Fluid flow control device 14 pumps or forces fluid from fluid source 12 through fluid pathway 16 into patient 20. In one embodiment, fluid flow control device 14 is a peristaltic or pulsatile infusion pump that operates on a regular cycle or frequency and provides a non-continuous or pulsatile fluid flow that pulsates at about the same frequency as the pumping frequency. In an alternate embodiment, flow control device 14 includes a valve that opens and closes in controlled time intervals to administer boluses of medication. Here, the flow can be driven by gravity, e.g., via a head height difference between source container 12 and a valving system between device 14 and patient 20. Alternatively a pressure producing devices such as a rubber-band around the container,

a pressure cuff, or source container 12 being constructed out of an elastomeric material applies pressure on the fluid within container 12 to device the infusion fluid to patient 20.

[0017] A flowrate sensor 26 is disposed along fluid pathway 16 at a location downstream of fluid flow control device 14. Flowrate sensor 26 detects and monitors the rate of fluid flow through the infusion system and produces a flowrate output signal. In one embodiment, the output signal is an analog output signal that can be expressed in volts, amperes or ticks of a counter. Fig. 2 illustrates one example of an analog output signal 28 from flowrate sensor 26, which monitors the flowrate of fluid through infusion system 10. In this example, output signal 28 from flowrate sensor 26 is measured in volts, and the signal is expressed in volts as a function of time. Additionally, the graph illustrates output signal 28 under normal flowrate conditions, generally designated at area 30, and flowrate conditions when an occlusion has occurred, generally designated at area 32.

[0018] Fluid flow device 14 can be a pulsatile or non-continuous infusion pump that operates at a certain pumping frequency. This type of pump creates a pulsatile fluid flow through the fluid pathway. The pulsatile fluid flow has a flowrate that varies at substantially the same frequency as the pumping frequency. Thus, as illustrated in Fig. 2, output signal 28 of flowrate sensor 26 also cycles at substantially the same frequency as the pumping frequency and includes peaks 34 and valleys 36. Patient and operator induced artifacts, such as movement by the patient, can also affect the flowrate and the flowrate senor output signal. For example, these artifacts can affect the frequency and amplitude of the output signal as shown at 38 and 40.

[0019] The infusion system 10 can also include a processing device 50, such a microprocessor, which is configured to communicate with the flowrate sensor 26 to receive the output signal therefrom. Communication between the flowrate sensor 26 and the processing device 50 can be through any method, such as by a data cable 51 or through wireless communication. The processing device 50 can include non-volatile memory 52 that contains suitable software for carrying out the methods and processes described below. The processing device 50 can also include random access memory ("RAM") memory 54 that can be used as a work place for processing and storing data

as necessary. An alarm 56 for signaling an occlusion is also in communication with the processing device. The alarm can be a visual display or an auditory indicator.

[0020] In one method of the present disclosure, the output signal of flowrate sensor 26 is analyzed and processed to quickly detect an occlusion within the infusion system and to reduce the number of false alarms. The method generally includes monitoring the output signal from a flowrate sensor and converting or filtering the signal with a noise reduction filter to suppress the peaks and valleys of the signal and the patient or operator induced artifacts. The filtered output signal is then compared against a predetermined threshold value to determine if an occlusion is located within the infusion system. In one embodiment, the predetermined threshold value is an expected value based on the pump setting. Optionally, the threshold value is calculated from a baseline of the output signal that is captured as fluid initially flows through the infusion circuit.

[0021] Referring now to Fig. 3, a flowchart showing one embodiment of a method 100 for detecting an occlusion within an infusion system is provided. The method 100 or portions of the method can be embodied in one or more software program, which is stored in one or more memory and executed by one or more processor. Additionally, the order of the steps may be changed, and some of the steps described may be optional.

[0022] Upon beginning method 100 at block 108, fluid is infused through the infusion system (pumped) at block 110. At block 112, a baseline of the output signal from the flowrate sensor is captured or acquired (e.g., taken and recorded) for a set period of time. The acquired baseline includes a set of data points including the strength of the output signal as a function of time. In one embodiment, the baseline is acquired as the infusion system is being primed. Alternatively, the baseline can be acquired as the fluid is initially infused into the patient. In one embodiment, the baseline is acquired for a time period between about ten seconds and about sixty seconds as the infusion system is being primed. When a pulsatile pump is used, the period of time in which the baseline is acquired can be based on a set number of pumping cycles of the pump.

[0023] After the baseline has been taken, turning to block 114, baseline 39 (shown in Fig. 2) is filtered or converted with a noise reduction or averaging filter to

calculate a baseline average and standard deviation. In one embodiment, the baseline is filtered with a backward averaging filter. The backward averaging filter can be software that converts or filters the baseline with a backward averaging or moving averaging equation. One suitable filtering software is provided by National Instruments, Austin, TX, under the name LabVIEW®.

[0024] In another embodiment, a ten second backward averaging filter is employed to obtain a baseline average. This filter converts the strength of the output signal of each baseline data point to an average of the data points acquired during the previous ten seconds. The collection of averaged data points forms the baseline average.

[0025] The averaging filter also can be other types of averaging filters such as a central averaging filter, a weighted averaging filter, a predictor-corrector type averaging filter or other averaging filter that is suitable for a plant model of the pump and delivery system. "Predictor-corrector" averaging filters typically include a method of predicting behavior of the 'plant' (in this case the infusion system), the corrector step then corrects this prediction using measured values.

[0026] Once the baseline average and standard deviation have been obtained, referring to block 116, a threshold value 41 (Fig. 4) is calculated. The threshold valve can be based on the baseline average, the standard deviation or both of these values. In one embodiment, the threshold value is the baseline average minus the standard deviation. In another embodiment, the threshold value is a percentage or a fraction of the baseline average. In yet another embodiment, the threshold value is not based on the baseline average, but instead is based on other factors, such as pump speed.

[0027] After the threshold value has been determined, at block 118, the output signal of the flowrate sensor is monitored. As discussed above, the output signal can be an analog signal. At block 120, the output signal is filtered or converted with a noise reduction filter, such as one of the averaging filters mentioned above. Converting the output signal with the noise reduction filter suppresses the peaks and valleys of the signal and also suppresses patient induced artifacts. For example, Fig. 4 illustrates a graphical comparison of output signal 28 (shown in dotted lines) and filtered output signal 42, which has been converted by an averaging filter (shown in a solid line). As can be seen by comparing output signal 28 and filtered output signal

42, applying a noise reduction filter to output signal 28 suppresses the peaks and valleys 34, 36 of signal 28 and the artifacts 38, 40.

[0028] At block 122, filtered signal 42 is then compared to threshold value 41. At block 124, method 100 determines if the filtered output signal is below the threshold value. If the filtered signal 42 is above the threshold value 41, for example at area 45 of the plot shown in Fig. 4, output signal 28 continues to be monitored, converted and compared to the threshold value. If filtered signal 42 falls below threshold value 41, for example at area 47 of the plot shown in Fig. 4, method 100 activates an alarm indicating that an occlusion has occurred, as shown in Block 126. The alarm can be any type of alarm, such as an auditory alarm or a visible alarm. Method 100 ends as seen at oval 128.

[0029] It should be appreciated that converting output signal 28 with a filter to suppress the peaks, valleys and artifacts of the signal reduces the chances of false alarms. For example, artifact 40 in Fig. 4 causes the output signal to fall below threshold level 41. If output signal 28 is not filtered, the artifact could trigger a false alarm. However, when the signal is converted with the filter, the artifact is suppressed, such that the level does not fall below the threshold, reducing the risk of false alarms.

[0030] In another embodiment of the present disclosure, when a pulsatile pump is used, an occlusion can be detected in an infusion system by comparing the strength of the flowrate sensor output signal at a selected range of frequency to a predetermined threshold level. As discussed above and referring again to Fig. 2, the pulsatile pump produces a pulsatile fluid flow having relatively the same frequency as the pumping frequency. The pulsatile fluid causes output signal 28 of the flowrate sensor to also have a frequency substantially similar to that of the pumping frequency. It has been found that an occlusion can be detected by comparing the signal strength of the output signal at the pumping frequency to an upper and/ or lower preset threshold level. Further, the general location of the occlusion can also be determined depending on such comparison.

[0031] Referring now to Fig. 5, a flowchart showing one embodiment of a method 200 for detecting an occlusion based on the strength of the output signal within a range of frequency is provided. The method 200 or portions of the method can be embodied in one or more software program which is stored in one or more memory

and executed by one or more processor. Further, the order of many of the steps may be changed, and some of the steps described may be optional.

[0032] Upon beginning method 200 at oval 208, fluid flows through the infusion system as seen at block 210. At block 212, the output signal from a flowrate sensor is monitored as the fluid is flowed through the infusion system. At block 214, a set of data is acquired or captured from the flowrate sensor for a predetermined period of time. The data set includes one of the types of output signals described above as a function of time.

[0033] At block 216, the data set is then filtered with a noise rejection filter to reduce noise that a patient or operator can cause, herein termed a patient or operator induced artifact. Such filters can include a low-pass frequency filter or a high-pass frequency filter. In one embodiment, the low-pass and high-pass frequency filters are provided in software that applies an algorithm to the data set. The algorithm filters out or attenuates (reduces the amplitude or frequency) frequency signals that are above a desired threshold and below a desired threshold. A low-pass frequency filter filters out or attenuates signals having frequencies that are higher than an upper threshold frequency. A high-pass frequency filter filters out or attenuates signals having frequencies below a lower threshold frequency. Software that includes such frequency filters can include the above mentioned LabVIEW® software.

[0034] After the filter has been applied, at block 218, power spectra analysis of the data set is preformed to determine the strength of the output signal per unit of frequency. Power spectra analysis transforms the data set from the time domain to the frequency domain signal, i.e., the date set is transformed from the output signal as a function of time to the strength of the signal as a function of frequency. Power spectra analysis can be performed by applying a Fourier transform algorithm to the filtered data set. In one embodiment, power spectra analysis is preformed on the filtered data set by analyzing the filtered data set with software, such as LabVIEW® software, which applies Fast Fourier Transform to the filtered data set.

[0035] At block 220, the signal strength of a frequency range that correlates to the pumping frequency is then calculated. In one embodiment, the frequency range is determined by identifying a pumping frequency, fp, and establishing a range based on the fraction of the pumping frequency, such as [fp – 0.2 * fp to fp + 0.2 * fp], or with a

broader range of, e.g., [fp – 0.35 * fp to fp + 0.35 * fp] or by applying an asymmetric bias towards lower frequencies for signal search such a fp – alpha * fp to fp + beta * fp, in which alpha and beta are within [0:1] and alpha > beta. Characteristic values for alpha might be 0.35 or 0.5 and those for beta might be 0.1 or 0.2. The signal strength in one embodiment is calculated by integrating the power-spectra in the frequency domain (the area under the power curve in the frequency domain) and computing the energy metric. At blocks 222 and 224, the signal strength of frequency range is then compared to a lower threshold and a higher threshold, respectively. The upper and lower thresholds can be expected valves based on various factors, such as the pump setting, viscosity of fluid being infused, length and diameter of the tubing lines and patient back pressure.

[0036] At block 226, method 200 determines if the signal strength of the frequency range is below the lower threshold level. If the strength is below the lower threshold, method 200 assumes that there is an occlusion upstream of the flowrate sensor and activates an alarm indicating same, as illustrated in block 228. If the signal strength is above the lower threshold, the method 200 proceeds to block 224. The reason that signal strength below the threshold indicates an occlusion upstream of the flowrate sensor is that an occlusion upstream of the flowrate sensor reduces the flowrate of fluid flowing past the sensor. This reduction of flowrate reduces the strength of the signal, which causes the signal strength to fall below the threshold.

[0037] Referring to block 224, the strength of the signal of the frequency range is compared to an upper threshold. At block 230, method 200 determines if the signal strength is above the upper threshold. If the signal strength is above the upper threshold, method 200 assumes an occlusion has occurred downstream of the flowrate sensor and activates an alarm indicating same, as depicted in block 232. If the signal strength is below the upper threshold valve, then method 200 continues to monitor the signal as illustrated in block 212. Method 200 ends at oval 234 or oval 236. The reason that signal strength above a pre-set threshold indicates an occlusion downstream of the flowrate sensor is that when the occlusion is downstream of the flowrate sensor, the sensor detects the rebound effect of the fluid bouncing off of the occlusion as more and more fluid is pumped into the infusion circuit. This rebound effect increases the strength of the sensor signal.

[0038] It will be understood that the steps of method 200 of comparing the signal strength to a lower threshold level and/or an upper threshold level can include comparing the strength only to the lower threshold level, only to the upper threshold level or both the upper and lower threshold level. Additionally, the signal strength can be compared to the lower threshold first, the upper threshold first or both the lower and upper thresholds simultaneously.

[0039] For pumping systems that generate pulsatile and/or intermittent (sequences with flow on and off) flowrate waveforms, another detection mode is possible. If the flow sensor is capable of measuring bi-directional flow (that is flow proximal and distal, with outputs that are identifiable) and significant compliance does exist between the flow sensor and the downstream occlusion; the occlusion can be detected through virtua of identification of bi-directional flow, negative and positive flow, through the flow sensor. The compliance between the flow sensor and occlusion ensures that there is some volume change in the fluid delivery set and as a result positive flow through the flow sensor is detected in an early portion of the cycle. During a pump filling portion of the cycle, the pressurized volume will leak backward causing detection of negative flow. Repeated presence of positive and negative flows can be interpreted as a presence of an occlusion. Alternatively, one can include a drip chamber, flexible tube or compliance chamber in the fluid delivery set placed downstream of the flow sensor.

[0040] It should be understood that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications can be made without departing from the spirit and scope of the present subject matter and without diminishing its intended advantages. It is therefore intended that such changes and modifications be covered by the appended claims.

CLAIMS

The invention is claimed as follows:

1. A method of detecting an occlusion within an infusion system comprising:

monitoring an output signal from a flowrate sensor as fluid flows through an infusion system;

filtering the output signal with a noise reduction filter to obtain a filtered output signal; and

activating an alarm if the filtered output signal falls below a threshold level.

2. The method of claim 1, which includes filtering the output signal with a backward averaging filter.

3. The method of claim 1, which includes filtering the output signal with a ten second averaging filter.

4. The method of claim 1, which includes continuously monitoring and filtering the output signal with the noise reduction filter.

5. The method of claim 1, which includes acquiring a baseline of the output signal of the flowrate sensor, and filtering the baseline with an averaging filter to calculate a baseline average, and calculating the threshold level as a function of the baseline average.

6. The method of claim 5, which includes calculating the standard deviation of the baseline average and calculating the threshold level by subtracting the standard deviation from the baseline average.

7. The method of claim 5, which includes calculating the threshold level as a percentage of the baseline average.

8. The method of claim 5, which includes filtering the baseline with a backward averaging filter.

9. The method of claim 5, which includes filtering the baseline with a ten second averaging filter.

10. The method of claim 1, which includes monitoring an analog output signal from the flowrate sensor.

11. A system configured to perform the steps of claim 1.

12. A method of detecting an occlusion within an infusion system, comprising:

monitoring an output signal from a flowrate sensor as a pulsatile fluid flow having a frequency flows through the infusions system;

acquiring a data set that includes the output signal as a function of time;

filtering the data set with a noise rejection filter to produce a filtered data set;

performing spectra analysis on the filtered data set to determine strength of the output signal in a frequency domain;

calculating a signal strength for a frequency range that correlates to the frequency of the pulsatile fluid flow; and

comparing the signal strength of the range to at least one threshold level to determine if an occlusion is present within the infusion system.

13. The method of claim 12, which includes calculating the signal strength of the range of frequency by integrating power spectra in a frequency domain for the frequency range and computing an energy metric.

14. The method of claim 12, which includes filtering the date set with a low-pass or a high-pass frequency filter.

15. The method of claim 12, which includes performing the spectra analysis by performing Fast Fourier Transform on the filtered data set.

16. The method of claim 12, which includes activating an alarm if the signal strength of the range of frequency is above the threshold level.

17. The method of claim 12, which includes activating an alarm if the signal strength of the range of frequency is below the threshold level.

18. The method of claim 12, which includes activating an alarm if the signal strength is above an upper threshold or below a lower threshold level.

19. A system configured to perform the steps of claim 12.

20. An infusion system, comprising:

a fluid pathway between a fluid source and a patient;

a flowrate sensor disposed along the fluid pathway, the flowrate sensor operable to produce an output signal;

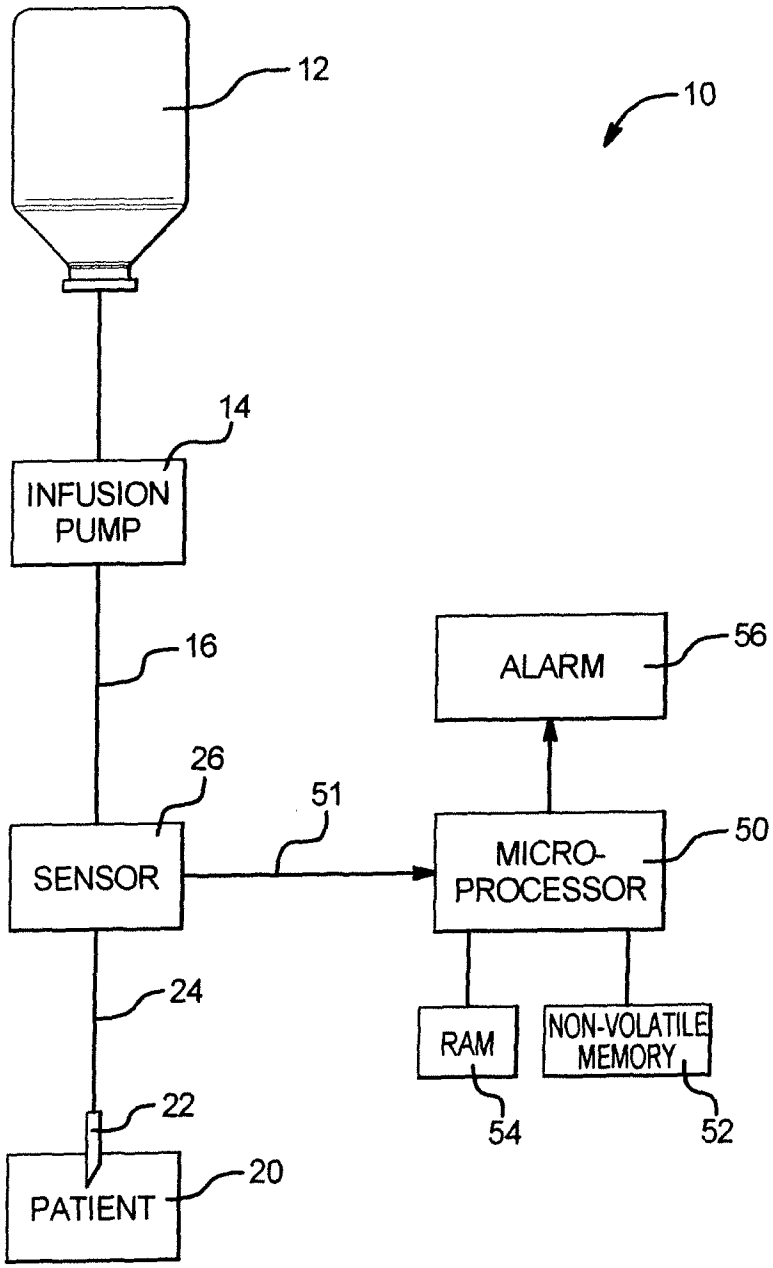
a processing device in communication with and receiving the output signal from the flowrate sensor, the processing device configured to apply a filter to the output signal to produce a filtered output signal; and

an alarm operable with the processing device to indicate when the filtered output signal falls below or rises above a predetermined threshold value.

21. The infusion system of claim 20, wherein the flowrate sensor is configured to produce an analog output signal.

22. The infusion system of claim 20, wherein the filter is of a type selected from the group consisting of: a backend averaging filter, a ten second averaging filter, a central averaging filter and a weighted averaging filter.

FIG. 1


12
10
14
INFUSION PUMP
16
ALARM
56
26
51
SENSOR
MICRO-PROCESSOR
50
24
RAM
NON-VOLATILE MEMORY
22
54
52
PATIENT
20

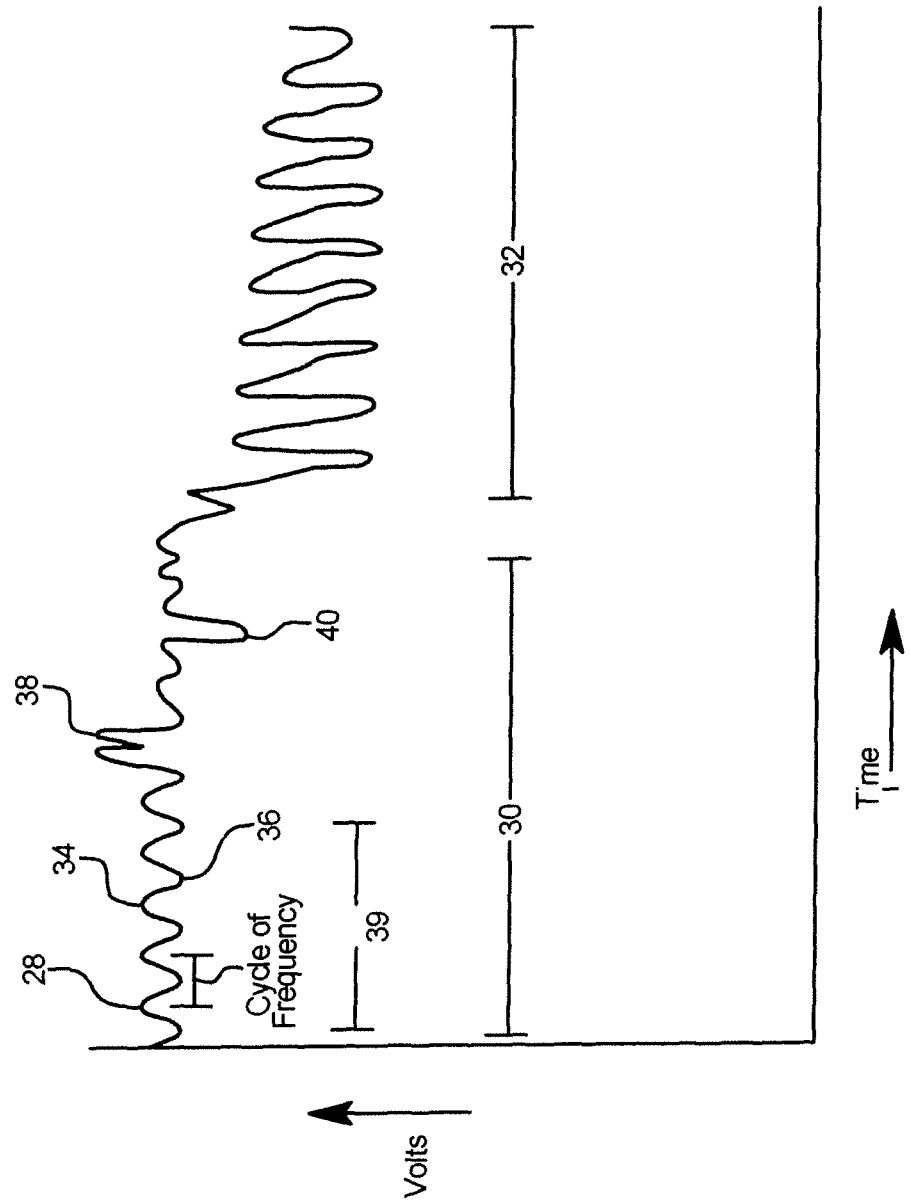
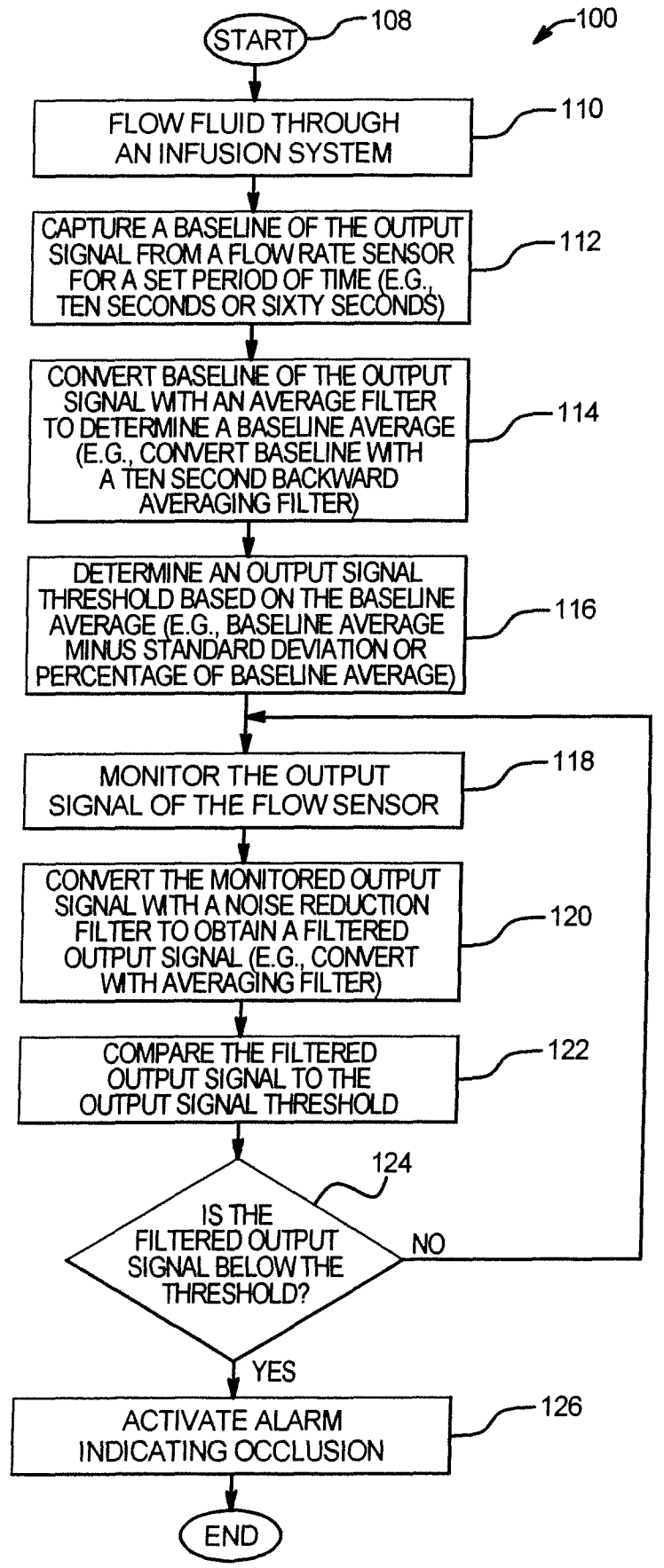


FIG. 2

FIG. 3


START
108
100
FLOW FLUID THROUGH AN INFUSION SYSTEM
110
CAPTURE A BASELINE OF THE OUTPUT SIGNAL FROM A FLOW RATE SENSOR FOR A SET PERIOD OF TIME (E.G., TEN SECONDS OR SIXTY SECONDS)
112
CONVERT BASELINE OF THE OUTPUT SIGNAL WITH AN AVERAGE FILTER TO DETERMINE A BASELINE AVERAGE (E.G., CONVERT BASELINE WITH A TEN SECOND BACKWARD AVERAGING FILTER)
114
DETERMINE AN OUTPUT SIGNAL THRESHOLD BASED ON THE BASELINE AVERAGE (E.G., BASELINE AVERAGE MINUS STANDARD DEVIATION OR PERCENTAGE OF BASELINE AVERAGE)
116
MONITOR THE OUTPUT SIGNAL OF THE FLOW SENSOR
118
CONVERT THE MONITORED OUTPUT SIGNAL WITH A NOISE REDUCTION FILTER TO OBTAIN A FILTERED OUTPUT SIGNAL (E.G., CONVERT WITH AVERAGING FILTER)
120
COMPARE THE FILTERED OUTPUT SIGNAL TO THE OUTPUT SIGNAL THRESHOLD
122
124
IS THE FILTERED OUTPUT SIGNAL BELOW THE THRESHOLD?
NO
YES
ACTIVATE ALARM INDICATING OCCLUSION
126
END

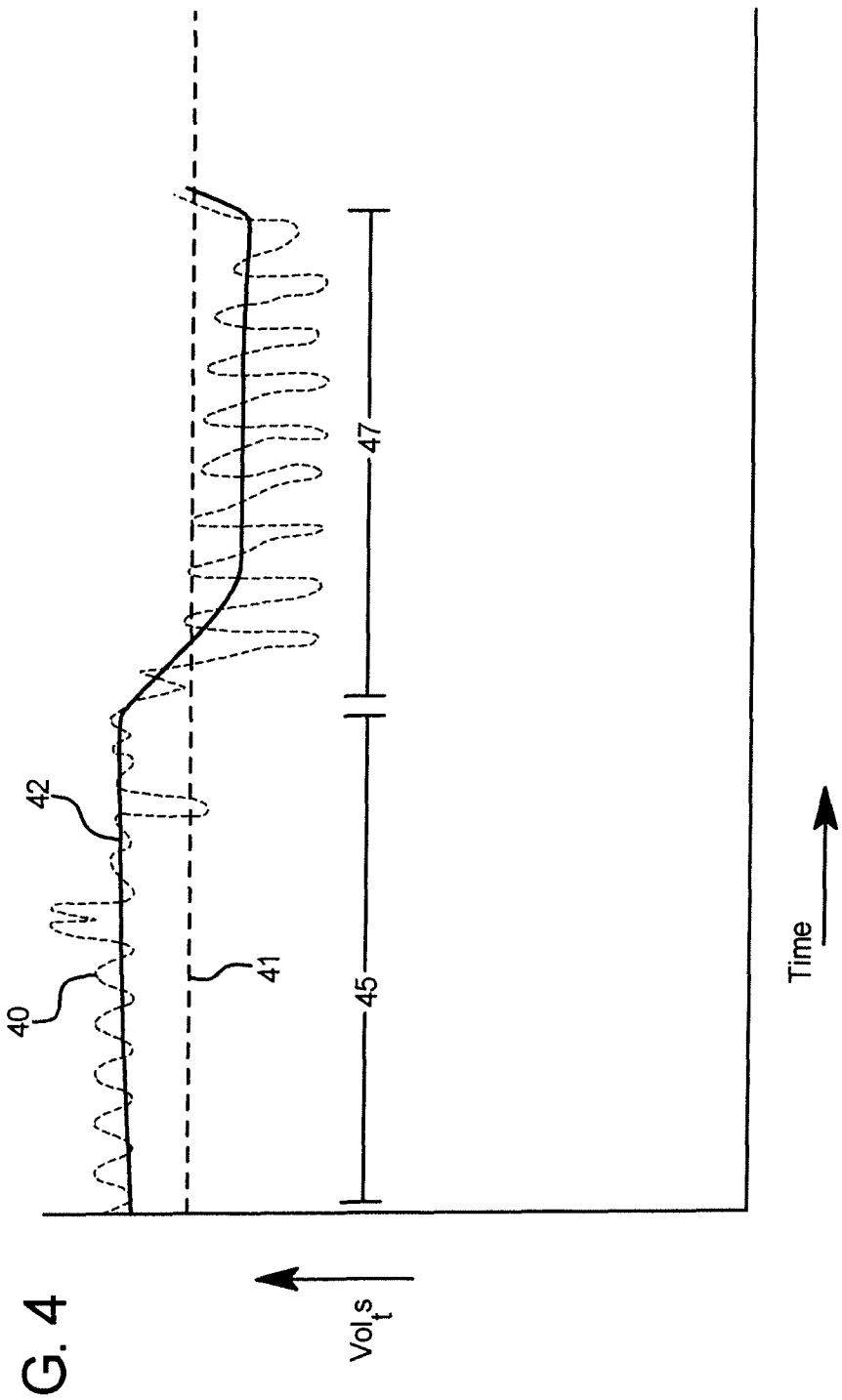
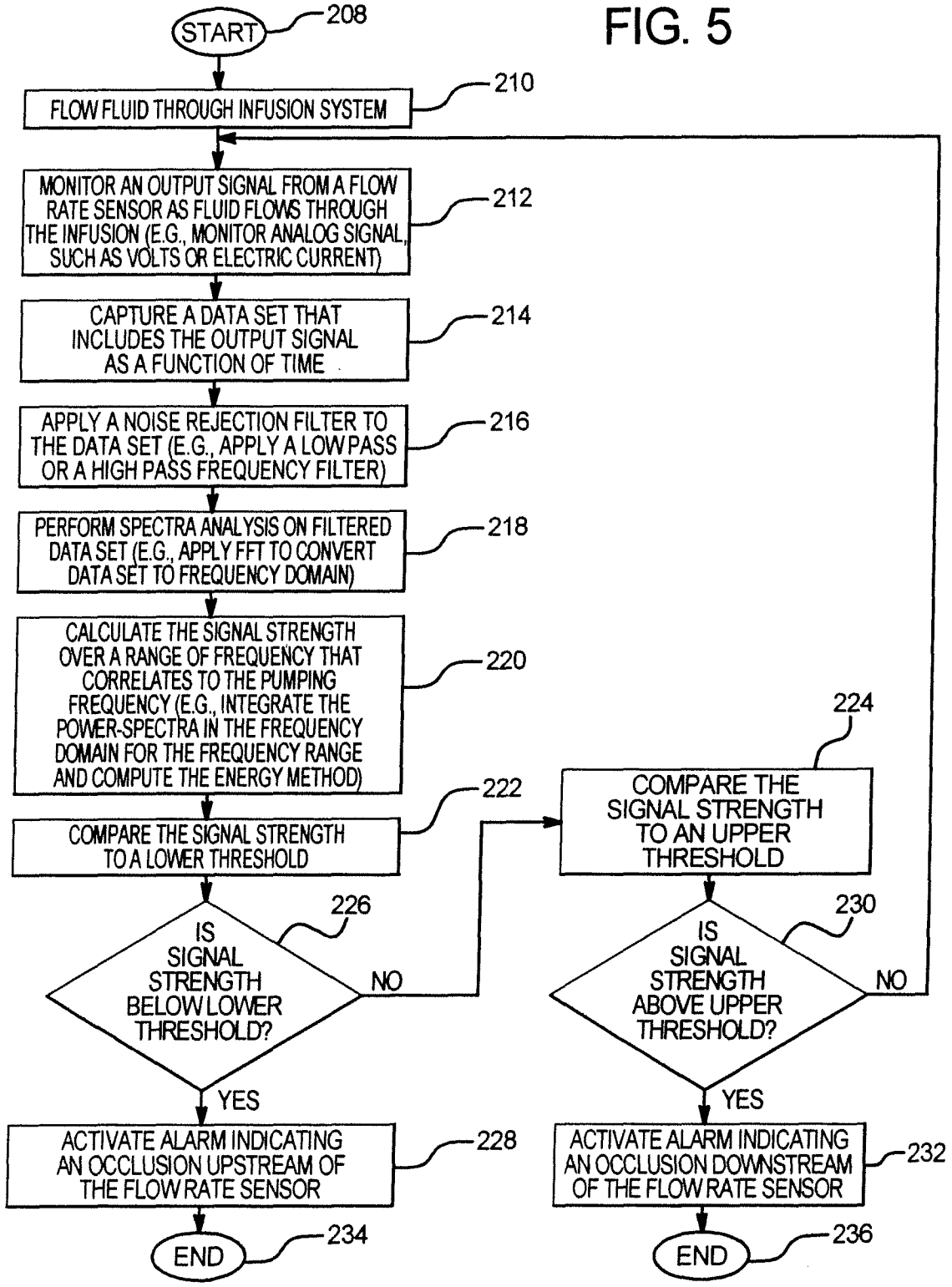


FIG. 4

FIG. 5


START
208
FLOW FLUID THROUGH INFUSION SYSTEM
210
MONITOR AN OUTPUT SIGNAL FROM A FLOW RATE SENSOR AS FLUID FLOWS THROUGH THE INFUSION (E.G., MONITOR ANALOG SIGNAL, SUCH AS VOLTS OR ELECTRIC CURRENT)
212
CAPTURE A DATA SET THAT INCLUDES THE OUTPUT SIGNAL AS A FUNCTION OF TIME
214
APPLY A NOISE REJECTION FILTER TO THE DATA SET (E.G., APPLY A LOW PASS OR A HIGH PASS FREQUENCY FILTER)
216
PERFORM SPECTRA ANALYSIS ON FILTERED DATA SET (E.G., APPLY FFT TO CONVERT DATA SET TO FREQUENCY DOMAIN)
218
CALCULATE THE SIGNAL STRENGTH OVER A RANGE OF FREQUENCY THAT CORRELATES TO THE PUMPING FREQUENCY (E.G., INTEGRATE THE POWER-SPECTRA IN THE FREQUENCY DOMAIN FOR THE FREQUENCY RANGE AND COMPUTE THE ENERGY METHOD)
220
COMPARE THE SIGNAL STRENGTH TO A LOWER THRESHOLD
222
IS SIGNAL STRENGTH BELOW LOWER THRESHOLD?
226
NO
YES
ACTIVATE ALARM INDICATING AN OCCLUSION UPSTREAM OF THE FLOW RATE SENSOR
228
END
234
COMPARE THE SIGNAL STRENGTH TO AN UPPER THRESHOLD
224
IS SIGNAL STRENGTH ABOVE UPPER THRESHOLD?
230
NO
YES
ACTIVATE ALARM INDICATING AN OCCLUSION DOWNSTREAM OF THE FLOW RATE SENSOR
232
END
236