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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
24 December 2003 (24.12.2003)

PCT

(10) International Publication Number
WO 03/105669 A2

(51) International Patent Classification[7]: A61B

(21) International Application Number: PCT/US03/18859

(22) International Filing Date: 13 June 2003 (13.06.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/319,318 14 June 2002 (14.06.2002) US

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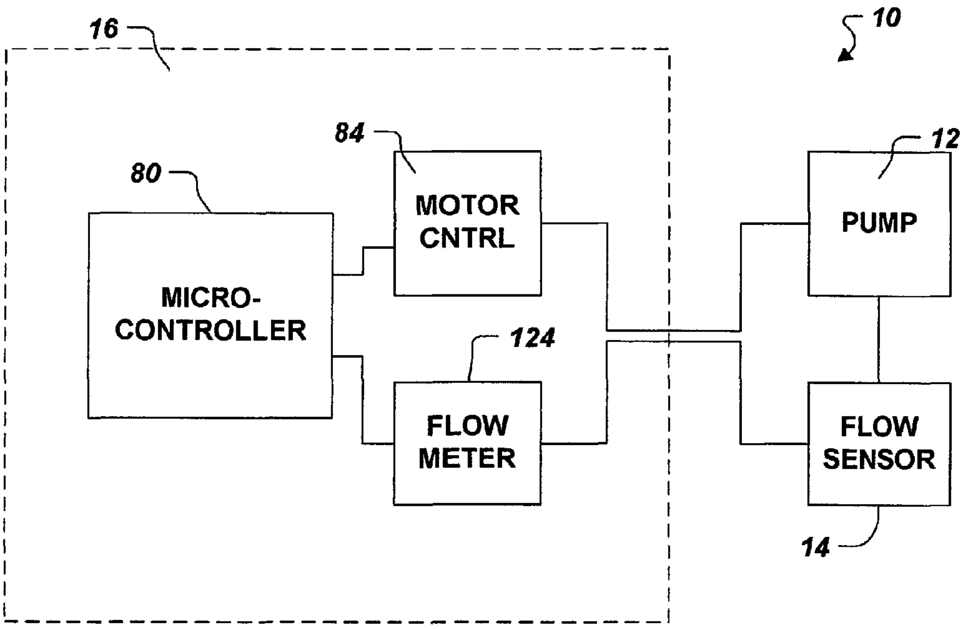
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) **Title:** METHOD AND SYSTEM FOR DETECTING VENTRICULAR SUCTION



(57) **Abstract:** Ventricular suction detection methods monitor or derive the blood flow waveform and analyze the waveform to detect suction. Suction is determined based on asymmetry of the flow waveform, plateaus in the flow waveform, and the slew rate of the flow waveform. Additionally, in accordance with other detection methods, the blood flow rate is analyzed to determine suction based on the mean flow rate falling to a predetermined low level and/or the relationship between maximum, mean and minimum flow. In accordance with still further detection methods, suction is determined based on "saddle" sequences (i.e., localized minimums or notches) in the falling arch of the flow peak.

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METHOD AND SYSTEM FOR DETECTING VENTRICULAR SUCTION

CROSS REFERENCE TO RELATED APPLICATION

This application claims the benefit of U.S. Provisional Application Serial Number 60/319,318, filed on June 14, 2002, which is incorporated by reference herein.

BACKGROUND OF THE INVENTION

1. FIELD OF THE INVENTION

The invention relates generally to blood pump systems, and more specifically, to a method and system for detecting the onset and/or presence of ventricular suction/collapse associated with such pumps.

2. DESCRIPTION OF RELATED ART

Generally, blood pump systems are employed in either of two circumstances. First a blood pump may completely replace a human heart that is not functioning properly, or second, a blood pump may boost blood circulation in patients whose heart is still functioning although pumping at an inadequate rate.

For example, U.S. Patent No. 6,183,412, which is commonly assigned and incorporated herein by reference in its entirety, discloses a ventricle assist device (VAD) commercially referred to as the "DeBakey VAD®." The VAD is a miniaturized continuous axial-flow pump designed to provide additional blood flow to patients who suffer from heart disease. The device is attached between the apex of the left ventricle and the aorta. Proper blood flow through the device depends on an adequately filled ventricle and a positive differential pressure between the inlet and the outlet of the VAD pump.

Since this device produces flow continually and actively fills, it has the potential to create low pressure at the inflow in order to produce flow. "Excess Suction" occurs when the pressure in the inflow cannula decreases significantly – the pump begins to "suck" the ventricle closed, which would greatly reduce the pumping capability of the native heart and VAD. Decreasing the VAD's speed during an excess suction condition would allow the ventricle to refill, and normal blood flow to resume. Additionally, the detection of ventricular collapse and the ability to automatically adjust the pump's speed may aid in maintaining correct blood flow to the patient.

Excess suction may be caused by occlusion of the tip of the inflow cannula or by completely emptying the ventricle (ventricular collapse).

In known pump systems, sustained excess suction typically triggers a diagnostic alarm on the pump controller. However, it would be desirable to detect the onset of suction prior to any physiologic effect. Further, known suction detection methods have been largely unsatisfactory.

The present invention addresses shortcomings associated with the prior art.

SUMMARY OF THE INVENTION

In accordance with aspects of the present invention, various methods for detecting ventricular suction in a patient having a blood pump are presented. The detection methods analyze the blood flow waveform to detect suction. The blood flow waveform may be monitored via a flow meter, or the flow waveform may be derived based on other system parameters. Suction is determined based on asymmetry of the flow waveform, plateaus in the flow waveform, and the slew rate of the flow waveform. Additionally, in accordance with other detection methods, the blood flow rate is analyzed to determine suction based on the mean flow rate falling to a predetermined low level and/or the relationship between maximum, mean and minimum flow. In accordance with still further detection methods, suction is determined based on "saddle" sequences (i.e. localized minimum, or notches) in the area of the flow waveform between peak systolic flow and minimum flow (i.e. in the trailing, or falling region of the flow waveform).

The various suction detection methods may be combined, wherein multiple or all of these methods for the flow are analyzed within every heartbeat (i.e. cardiac cycle time period), which leads to separate results for each detection method. Further, the results of the various detection methods may be weighted and the parameters set for optimal sensitivity and specificity using an automated comparison of a variation of parameter settings and algorithm weights with a classification done by human experts. This delivers, for a given set of example patterns, an optimal selection of weights and threshold parameters to minimize the number of false positive and false negative decisions.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects and advantages of the invention will become apparent upon reading the following detailed description and upon reference to the drawings in which:

FIG. 1 schematically illustrates various components of an implantable pump system in accordance with embodiments of the present invention;

FIG. 2 is a cross-section view of an exemplary implantable pump in accordance with embodiments of the present invention;

FIG. 3 is a block diagram illustrating aspects of a controller module in accordance with embodiments of the present invention; and

FIGs. 4A and 4B are flow charts illustrating a heart rate detection process in accordance with embodiments of the present invention;

FIGs. 5A and 5B are flow charts illustrating a local flow maximum detection function in accordance with embodiments of the present invention;

FIGs. 6A and 6B are flow charts illustrating a local flow minimum detection function in accordance with embodiments of the present invention;

FIG. 7 is a chart conceptually illustrating changes between an artificially generated clock signal and actual maximum or minimum flow detection;

FIG. 8 is a graph showing the filtered flow signal response in the frequency and phase domain;

FIG. 9 conceptually illustrates a digital low pass filter using a sliding algorithm in accordance with embodiments of the present invention;

FIGs. 10A and 10B are flow charts illustrating a mean flow calculation and the use thereof in accordance with embodiments of the present invention;

FIGs. 11A and 11B are flow charts illustrating a mean current calculation and the use thereof in accordance with embodiments of the present invention;

FIGs. 12A and 12B are flow charts illustrating a flow waviness calculation and the use thereof in accordance with embodiments of the present invention;

FIGs. 13A and 13B are flow charts illustrating an asymmetry detection function based on local flow minimum detection in accordance with embodiments of the present invention;

FIGs. 14A and 14B are flow charts illustrating an asymmetry detection function based on local flow maximum detection in accordance with embodiments of the present invention;

FIG. 15 is a chart illustrating thresholds used in a plateau detection algorithm for detection suction in accordance with embodiments of the present invention;

FIGs. 16A and 16B are flow charts illustrating a plateau detection process in accordance with embodiments of the present invention;

FIG. 17 is a flow chart illustrating a slew rate detection process in accordance with embodiments of the present invention;

FIG. 18 is a flow chart illustrating a low flow detection process in accordance with embodiments of the present invention;

FIG. 19 is a graph conceptually illustrating a function for evaluating mean, maximum and minimum flow criteria;

FIG. 20 is a flow chart illustrating a process for evaluating mean, maximum and minimum flow relationships using maximum flow detection for an evaluation window length determination;

FIG. 21 is a flow chart illustrating a process for evaluating mean, maximum and minimum flow relationships using minimum flow detection for an evaluation window length determination;

FIG. 22 is a graph illustrating waveforms showing suction patterns containing "saddle" sequences (i.e. localized minimum, or notches) in the area of the flow waveform between peak systolic flow and minimum flow (i.e. in the trailing, or falling region of the flow waveform);

FIG. 23 is a flow chart illustrating a saddle detection algorithm in accordance with embodiments of the present invention;

FIGs. 24A and 24B are flow charts illustrating a flow signal validation process in accordance with embodiments of the present invention;

FIG. 25 is a flow chart of an overall suction detection algorithm.

While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof have been shown by way of example in the drawings and are herein described in detail. It should be understood, however, that the description herein of specific embodiments is not intended to limit the invention to the particular forms disclosed, but on the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF THE INVENTION

Illustrative embodiments of the invention are described below. In the interest of clarity, not all features of an actual implementation are described in this specification. It will of course be appreciated that in the development of any such actual embodiment, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking for those of ordinary skill in the art having the benefit of this disclosure.

Turning to the figures, FIG. 1 illustrates a ventricle assist device (VAD) system 10 such as disclosed in U.S. Patent No. 6,183,412, which is commonly assigned and incorporated herein by reference in its entirety. The VAD system 10 includes components designed for implantation within a human body and components external to the body. Implantable components include a rotary pump 12 and a flow sensor 14. The external components include a portable controller module 16, a clinical data acquisition system (CDAS) 18, and a patient home support system (PHSS) 20. The implanted components are connected to the controller module 16 via a percutaneous cable 22.

The VAD System 10 may incorporate an implantable continuous-flow blood pump, such as the various embodiments of axial flow pumps disclosed in U.S. Patent No. 5,527,159 or in U.S. Patent No. 5,947,892, both of which are incorporated herein by reference in their entirety. An example of a blood pump suitable for use in an embodiment of the invention is illustrated in FIG. 2. The exemplary pump 12 includes a pump housing 32, a diffuser 34, a flow straightener 36, and a brushless DC motor 38, which includes a stator 40 and a rotor 42. The housing 32 includes a flow tube 44 having a blood flow path 46 therethrough, a blood inlet 48, and a blood outlet 50.

The stator 40 is attached to the pump housing 32, is preferably located outside the flow tube 44, and has a stator field winding 52 for producing a stator magnetic field. In one embodiment, the stator 40 includes three stator windings and may be three phase "Y" or "Delta" wound. The rotor 42 is located within the flow tube 44 for rotation in response to the stator magnetic field, and includes an inducer 58 and an impeller 60. Excitation current is applied to the stator windings 52 to generate a rotating magnetic field. A plurality of magnets 62 are coupled to the rotor 42. The magnets 62, and thus the rotor 42, follow the rotating magnetic field to produce rotary motion.

FIG. 3 conceptually illustrates aspects of the pump system 10. More specifically, portions of the controller module 16 and the pump 12 are shown. The controller module 16 includes a processor, such as a microcontroller 80, which in one embodiment of the invention is a model PIC16C77 microcontroller manufactured by Microchip Technology. The microcontroller 80 includes a multiple channel analog to digital (A/D) converter, which receives indications of motor parameters from the motor controller 84. Thus, the controller module 16 may monitor parameters such as instantaneous motor current, motor voltage, and motor speed.

The embodiment shown in FIG. 3 further includes an integral flow meter 124. At least one flow sensor 14 is implanted down stream of the pump 12. Alternately, a flow sensor 14 may be integrated with the pump 12. The flow meter 124 is coupled between the implanted flow sensor 14 and the microcontroller 80. The flow meter 124 receives data from the flow sensor 14 and outputs flow rate data to the microcontroller 80, allowing the system to monitor instantaneous flow rate.

Since the implanted flow sensor 14 is coupled to the flow meter 124 of the controller module 16, a true measure of system performance (flow rate) is available for analysis, in addition to pump parameters such as motor speed and current (power). Further, since the flow meter 124 is an integral component of the controller module 16, flow rate may be displayed on the controller module display and flow rate data may be saved in the controller module memory.

In exemplary embodiments of the invention, the motor controller 84 comprises a MicroLinear ML4425 Motor Controller. The operation of the brushless DC motor 38 of the present invention requires that current be applied in a proper sequence to the stator windings 52 to create the rotating field. Two stator windings 52 have current applied to them at any one time, and by sequencing the current on and off to the respective stator windings 52, the rotating magnetic field is produced. In an embodiment of the invention, the motor controller 84 senses back electromotive force (EMF) voltage from the motor windings 52 to determine the proper commutation phase sequence using phase lock loop (PLL) techniques. Whenever a conductor, such as a stator winding 52, is "cut" by moving magnetic lines of force, such as are generated by the magnets 62 of the brushless DC motor 38, a voltage is induced. The voltage will increase with rotor speed 42. It is possible to sense this voltage in one of the three stator windings 52 because only two of the motor's windings 52 are activated at any one time, to determine the rotor 42 position.

An alternative method of detecting the rotor 42 position relative to the stator 40 for providing the proper stator winding 52 excitation current sequence is to use a position sensor, such as a Hall effect sensor. Implementing aspects of the present invention using a motor with rotor position sensors, rather than a sensorless motor, would be a routine undertaking for one skilled in the art having the benefit of this disclosure. However, adding additional components, such as Hall effect sensors, requires additional space, which is limited in any implanted device application. Further, using a position detection device adds sources of system failures.

Among other things, the CDAS 18 is used to adjust the speed of the pump and also monitors and stores data regarding operation of the pump 12, including pump flow, pump current and, if available, arterial pressure . These sampling rates are exemplary and may vary depending on the specific system configuration.

The suction detection methods and systems described herein are primarily intended to detect suction at the inlet 48 of the VAD pump 12, but may also be applied to other implanted rotary pumps, including those with indirectly determined flow. Such suction could be correlated, for example, with hemolysis, endothelial trauma, subsequent pannus formation, arrhythmia, and increased required power, and in case of complete collapse, also massive reduction of pump flow. The disclosed methods provide reliable and immediate information on suction, and are intended generally first to activate visible and/or audible alarms, and second to modify operation of the pump 12 to prevent too high pumping speeds.

The motor controller 84 operates to maintain the pump 12 at an essentially constant speed regardless of the differential pressure across the pump or the flow through the pump. As noted above, the motor controller 84 uses a PLL to control the speed of the pump motor 38 (commutation control). An additional analog closed-loop control circuit controls the onboard pulse width modulator (PWM) to maintain a desired speed setting. Both control-loops work in unison to maintain proper speed control.

In accordance with certain aspects of the present invention, suction detection is based on the pump flow signal. It is possible to distinguish between normal pumping conditions and suction by using the flow signal only, isolating distinct characteristics in the flow pattern that are indicators for potential suction events. In addition to the flow signal, the pump speed and current (power) signals may be used for suction detection. The automatic suction detection methods disclosed herein can decide between normal condition and suction within one heart cycle. This simplifies the detection algorithm and minimizes the risk of errors due to atypically following consecutive events. Therefore, suction indicators are calculated on a beat-to-beat basis. This allows reacting to upcoming suction immediately.

In an exemplary embodiment of the invention, the suction detection system runs at a sampling frequency of f_s = 100 Hz. Certain portions of the system are triggered by other processes. At least three different triggers are involved in the suction detection system, which start other calculation processes or parts of them. These triggers include

Heart rate sync pulse – triggered by zero-crossing of flow in time domain, or, in case of missing pulsatility, by a hardware clock. This provides a trigger for the calculation of mean flow, mean current and flow waviness.

Maximum detection – triggered after having detected a distinct maximum in the flow pattern. This provides trigger pulses for "relation between mean, minimum and maximum flow" criteria.

Minimum detection – triggered after having detected a distinct minimum in the flow pattern. This provides trigger pulses for the "relation between mean, minimum and maximum flow" criteria and flow asymmetry detection.

The flow signal of continuous LVADs such as the pump 12 is modulated by the patient's beating heart. It is therefore possible even at most low levels of contractility to derive the heart rate using the pump flow signal. An exemplary heart rate detection process is shown in FIGs. 4A and 4B. It is based on the filtered flow signal (for exemple a FIR-filter 16th-Order, f_{cutoff} = 5Hz). In the illustrated process, the DC-offset is eliminated by linear interpolation in a least square sense. The duration between consecutive zero crossings is evaluated and approximates the heart period of the last heart cycle. This heart rate detection algorithm is appropriate for most clinical situations; however there are situations where no heart rate detection is possible due to, for example, fibrillation, complete left heart failure, suction events, severe arrhythmia with massive bradycardia, very low flow waviness at complete left ventricular unloading, etc.

The upper limit for a detectable heart period is set to 2 seconds – a 30 beat/min heart rate. If no pulsatility, or waviness, is detected by this time limit, the output of the heart rate detection function is set to 30 beat/min and an automatic clock is generated for the connected trigger signal receiver. After each flow signal independent trigger, the detection of consecutive zero crossing events is disabled during a 50 ms period. A hysteresis function is employed to reduce sensitivity.

As noted above, suction detection is evaluated beat by beat. Hence, a stable synchronicity with the flow waviness is necessary. In certain situations, such synchronicity may not be provided sufficiently by the heart rate detection algorithm alone, because of the low-frequency shifts of the flow signal. Therefore, a trigger from the local flow maximum was derived, which indicates the start and end of the actual heart circle. FIGs. 5A and 5B illustrate a maximum detection function in accordance with an embodiment of the invention.

In the case of no maximum flow detections during within a predetermined time period, the illustrated process automatically activates a clock generator. The pulses created by this generator in equidistant intervals then replace the (non) detected flow maximum.

Because some algorithms are more sensitive to minimum flow detection than maximum flow detection, a trigger from the local flow minimum is also derived, which indicates start and end of the actual heart circle based on minimum timing. FIGs. 6A and 6B illustrate a minimum detection function in accordance with embodiments of the present invention. As with the maximum flow detections, in the case of no minimum detections during a predetermined time period a clock generator is activated. The pulses created by this generator in equidistant intervals replace the (non)detected flow minimum.

Upon detecting an actual flow maximum or minimum following "artificial," or automatically generated pulses, the clock timer is reset but does not trigger the suction algorithms. FIG. 7 illustrates how the change between the artificially generated clock signal and an actual maximum or minimum flow detection can lead to wrong results.

In certain exemplary embodiments of the invention, the suction detection algorithms use parameters that are derived from the flow signal, and therefore, are calculated in advance of the algorithms themselves. For example, in one implementation, the system includes one discrete FIR 16^{th}-order filter with a cut off frequency *fcutoff* = 5 Hz. FIG. 8 illustrates the filter response in the frequency domain, showing the magnitude and phase response of the FIR-16th-order filter.

The flow calculation is calculated from the raw flow signal. To avoid disturbances caused by noise or other uncertainties a simple sliding mean algorithm is used. The calculation, which is based on the unfiltered pump flow signal, is shown in FIG. 9. Two arithmetic mean values are evaluated from 14 consecutive flow value sampled at 100 Hz. These two mean values (Flowmean1 and Flowmean2) are used to evaluate the actual flow derivation.

The mean flow, mean current, and flow waviness parameters are triggered by the heart rate detection in the time domain and provide basic information for suction detection and physiological control system. Each of these parameters is evaluated beat-to-beat using the heart rate detection as its trigger source. In the case of no flow waviness or an uncertain flow pattern, which may prevent reliable heart rate detection, the "artificial" clock will trigger the calculations in equidistant time steps of two seconds. FIGs. 10A and 10B illustrate the mean flow calculation, FIGs. 11A and 11B illustrate the mean current calculation and the flow waviness calculation is illustrated in FIGs. 12A and 12B.

In an exemplary embodiment, the current signal is available at a sample rate of $f_s = 2{,}000$ Hz. For the mean current calculation, it is sufficient to use a down-sampled current signal of $f_s = 100$ Hz. However, for other purposes, the high sampling frequency may be desirable. For the waviness calculation, a filtered flow signal is used instead of the raw flow signal to reduce the influence of noise peaks on the evaluated flow waviness value.

Several suction indicators are discussed as follows:

Asymmetry Detection—

During suction events, the falling flanks during one period are often considerably steeper than the rising flanks. This is vice versa to the normal flow pattern where the rising edges are steeper than the falling ones. Accordingly, in accordance with aspects of the invention, $\frac{d}{dt}Q_{max}$ and $\frac{d}{dt}Q_{min}$ are calculated, respectively, within a time window. The time between two subsequent flow maximums or minimums is used to determine the size of the time window. If the duration of the window is too long, flanks of different heartbeats will be compared, whereas if it is too short, the windows may exclude the real maximum or minimum.

Within the actual time window the following equation is used to detect possible suction events:

$$\mathrm{Abs}\left(\frac{d}{dt}Q_{max}\right) - \mathrm{Abs}\left(\frac{d}{dt}Q_{min}\right) < \mathrm{Asym}_{Threshold} \bullet \frac{\mathrm{l/min}}{\mathrm{sec}}$$

FIGs. 13A and 13B are flow charts illustrating the asymmetry detection function based on local flow minimum detection, and FIGs. 14A and 14B illustrate asymmetry detection function based on local flow maximum detection. In FIGs. 13 and 14, *Dermax* is the maximum flow derivation (liter/min/sec), *Dermin* is the minimum flow derivation (liter/min/sec) and *Deract* is the actual value of flow derivation (liter/min/sec).

Plateau Detection—

The plateau detection suction indicator can be divided in three consecutive phases. Phase 1 is a sequence of very low waviness. It is detected using the flow derivation. Plateaus are detected if the absolute value of the flow derivation stays below a predetermined flow during a desired time period, for example, 3 liter/min/sec during 140 ms. In phase 2, the flow decreases after the plateau. For a valid suction detection, the flow derivation has to be lower than some predetermined flow, for example, –7 liter/min/sec. Phase 3 is a consecutive increase in pump flow. If the flow derivation increases above a predetermined rate during a set time period following phase 2, suction is detected.

Phase 3 is very important concerning patterns with very low frequency and distinct plateaus on the top of each flow peak. These peaks are followed by a normal negative slew rate and a consecutive very low flow increase. For avoiding additional false detections caused by such a pattern, the plateau detection criteria is extended by considering the consecutive flow increase following phase 1 and phase 2.

The six exemplary threshold values mentioned above are shown in FIG. 15. Plateaus are detected if the flow derivation is lower than 3 liter/min/sec during 0.14 seconds. A consecutive flow increase of greater than 5 liter/min/sec suppresses any detection. For a valid detection the plateau has to be followed by a flow decrease less than –7 liter/min/sec and a consecutive increase greater than 7 liter/min/sec within 0.4 seconds after the flow decrease. After the first plateau detection, a timer is started that will be cleared at each further plateau event. If this timer exceeds a predetermined time period without passing through phase 2, no suction detection will be accepted without a new detected plateau. Flow charts illustrating suction detection via plateau detection is shown in FIGs. 16A and 16B.

Slew Rate Detection—

Suction events with very high falling slew rates can be distinguished from certain flow patterns by observing the first flow derivation only. Therefore, the actual value of the flow derivation will be compared with a predetermined threshold value. If the actual flow derivation in liter/min/sec crosses the threshold value, a suction event is detected. This criterion only focuses on negative slew rates so the only negative threshold values are allowed. FIG. 17 is a flow chart illustrating slew rate detection.

Low Flow Detection—

In certain situations, a patient's ventricle can collapse completely. Such cases are very critical situations and make an additional suction criterion necessary. As a first condition for detecting suction using the low flow criterion, the mean flow has to be below 1.5 liter/min. If such a low mean flow occurs, the algorithm distinguishes between suction caused by compete collapse and backflow conditions. Backflow events are recognized if the raw pump flow decreases below a predetermined flow for a predetermined time period, for example, –0.2 liter/min during at least 50 ms. Suction will be detected if the pump flow decreases below 0.5 liter/min for at least 250 ms without any backflow detection and a mean flow below 1.5 liter/min. FIG. 18 is a flow chart illustrating the low flow detection algorithm. In FIG. 18, *Flowmean* is the mean pump flow (liter/min) and *Flow* is the raw pump flow (liter/min).

Relation Between Maximum, Mean and Minimum Flow—

Another indicator for suction, in accordance with embodiments of the invention, involves an evaluation of the relation between the mean flow, maximum flow and the minimum flow within one heart cycle. In the case of suction, the mean flow value is similar to the maximum flow value. This criterion is very sensitive to negative peaks, even if their slew rates are limited to normal values. The function to evaluate the MeanMinMax criterion is illustrated in FIG. 19. As with the asymmetry detection algorithm, the duration of the time window used for the evaluation of mean, maximum and minimum flow is important. The window time length is determined in the same manner as for asymmetry detection, based on either the time between two local flow minimums or maximums.

FIGs. 20 and 21 illustrate suction detection based on the relation between mean, maximum and minimum flow using maximum flow detection (FIG. 20) and minimum flow detection (FIG. 21) for the window length determination. In FIGs. 20 and 21, Q_{sum} = Actual sum of the individual raw pump flow samples between two consecutive flow maximums, Q_{mean} = Actual mean flow between two consecutive flow maximums, Q_{min} = Actual min flow between two consecutive flow maximums, Q_{max} = Actual max flow between two consecutive flow maximums, n = Number of sample between two consecutive flow maximums, and *Flowact* = Actual raw pump flow.

Saddle Detection—

FIG. 22 illustrates waveforms showing suction patterns containing saddle sequences in the falling arch of the flow peak. As noted previously, "saddle" sequences refer to localized minimums, or notches in the area of the flow waveform between peak systolic flow and minimum flow (i.e. in the trailing, or falling region of the flow waveform).

As with the plateau detection algorithm, the saddle detection function can be divided in three different phases. In phase 1, flow decrease is detected by comparison of the flow derivation with a threshold value, for example –20 liter/min/sec. Phase 2 is defined by consecutive low flow derivation for example, between –3 liter/min/sec and 5.5 liter/min/sec. After phase 1 and phase 2, in phase 3 a suction event is detected if the flow pattern shows a second decrease defined by a fourth threshold value of –15 liter/min/sec for example. These particular flow values are exemplary only. FIG. 23 is a flow chart illustrating the saddle detection algorithm.

As noted above, the suction detection algorithms disclosed herein are based on the pump flow signal delivered by the flow sensor 14. Accordingly, suction detection is disabled if there are problems with the raw flow signal. Several different indicators are used in the determination to disable automatic suction detection:

1.) Pump current is below a predetermined level, for instance, 0.1 A. With this current level, it is assumed that the pump is stopped and no suction detection is therefore necessary.

2.) Flow changes within two samples more than a predetermined amount, such as 4 liter/min. Slew rates of 400 liter/min/sec are not physiological and must therefore be excluded.

3.) Positive noise peaks are defined as, for example, a change of the flow value within one time step of 1 liter/min and a consecutive decrease of -1 liter/min within the next two sample values.

4.) Negative noise peaks, which are classified as noise if the flow decreases within one time step by, for example, about –2 liter/min followed by an increase of 2 liter/min during two sample times.

In exemplary embodiments of the invention, if any one of these four events occurs, the suction detection is disabled. It is automatically restarted if no further detection is recognized during some predetermined time period, for example, 5 seconds. FIGs. 24A and 24B show a flow chart of the flow signal validation, in which Q = actual raw pump flow (liter/min), Qz^{-2} = raw pump flow two samples ago (liter/min) and Qz^{-3} = raw pump flow three samples ago (liter/min).

FIG. 25 conceptually illustrates a suction detection system employing the suction detection methods described above. The illustrated system uses several suction detection algorithms: low flow detection, slew rate detection, plateau detection, saddle detection, relation of mean, minimum and maximum flow (based on flow maximum), relation of mean, minimum and maximum flow (based on flow minimum) and asymmetry detection. Inputs for these algorithms are include raw flow signal, filtered flow (5Hz), flow derivation, mean flow, trigger 1: maximum detection, trigger 2: Minimum detection and trigger 3: heart rate detection. For the maximum and minimum detections, the 5Hz-flow filter is necessary, which is also used for the evaluation of heart rate and flow waviness. The outputs of the suction detection algorithms are received by a decision block, where the flow signal is validated. If the signal is valid, an alarm is activated and pump parameters are adjusted in response to suction detection. If the signal is not valid, the suction detection is disabled.

In various embodiments of the invention, the aforementioned methods for detecting the imminence of ventricular collapse are implemented in software, hardware, or both. Software implementations include using the microcontroller 80 used provided in the controller module 16. Alternatively, a stand-alone microcontroller or a digital signal processor ("DSP"), for example, may be used. Exemplary hardware implementations may include a field programmable gate array ("FPGA"), a complex programmable logic device ("CPLD"), application specific integrated circuits ("ASIC"), discrete analog and/or digital components, etc.

The particular embodiments disclosed above are illustrative only, as the invention may be modified and practiced in different but equivalent manners apparent to those skilled in the art having the benefit of the teachings herein. Furthermore, no limitations are intended to the details of construction or design herein shown, other than as described in the claims below. It is therefore evident that the particular embodiments disclosed above may be altered or modified and all such variations are considered within the scope and spirit of the invention. Accordingly, the protection sought herein is as set forth in the claims below.

CLAIMS:

1. A method of detecting ventricular suction in a patient having a blood pump implanted, the method comprising:

analyzing a waveform of the patient's blood flow; and

determining the presence of ventricular suction based on asymmetry of the flow waveform.

2. A method of detecting ventricular suction in a patient having a blood pump implanted, the method comprising:

analyzing a waveform of the patient's blood flow; and

determining the presence of ventricular suction based on plateaus in the flow waveform.

3. A method of detecting ventricular suction in a patient having a blood pump implanted, the method comprising:

analyzing a waveform of the patient's blood flow; and

determining the presence of ventricular suction based on the slew rate of the flow waveform.

4. A method of detecting ventricular suction in a patient having a blood pump implanted, the method comprising:

analyzing a waveform of the patient's blood flow; and

determining the presence of ventricular suction based on the flow rate.

5. The method of claim 4, wherein determining the presence of ventricular suction based on the flow rate includes determining suction based on the mean flow rate falling to a predetermined low level.

6. The method of claim 4, wherein determining the presence of ventricular suction based on the flow rate includes determining suction based on the relationship between maximum, mean and minimum flow.

7. A method of detecting ventricular suction in a patient having a blood pump implanted, the method comprising:

analyzing a waveform of the patient's blood flow; and

determining the presence of ventricular suction based on localized minimumin the area of the flow waveform between peak systolic flow and minimum flow.

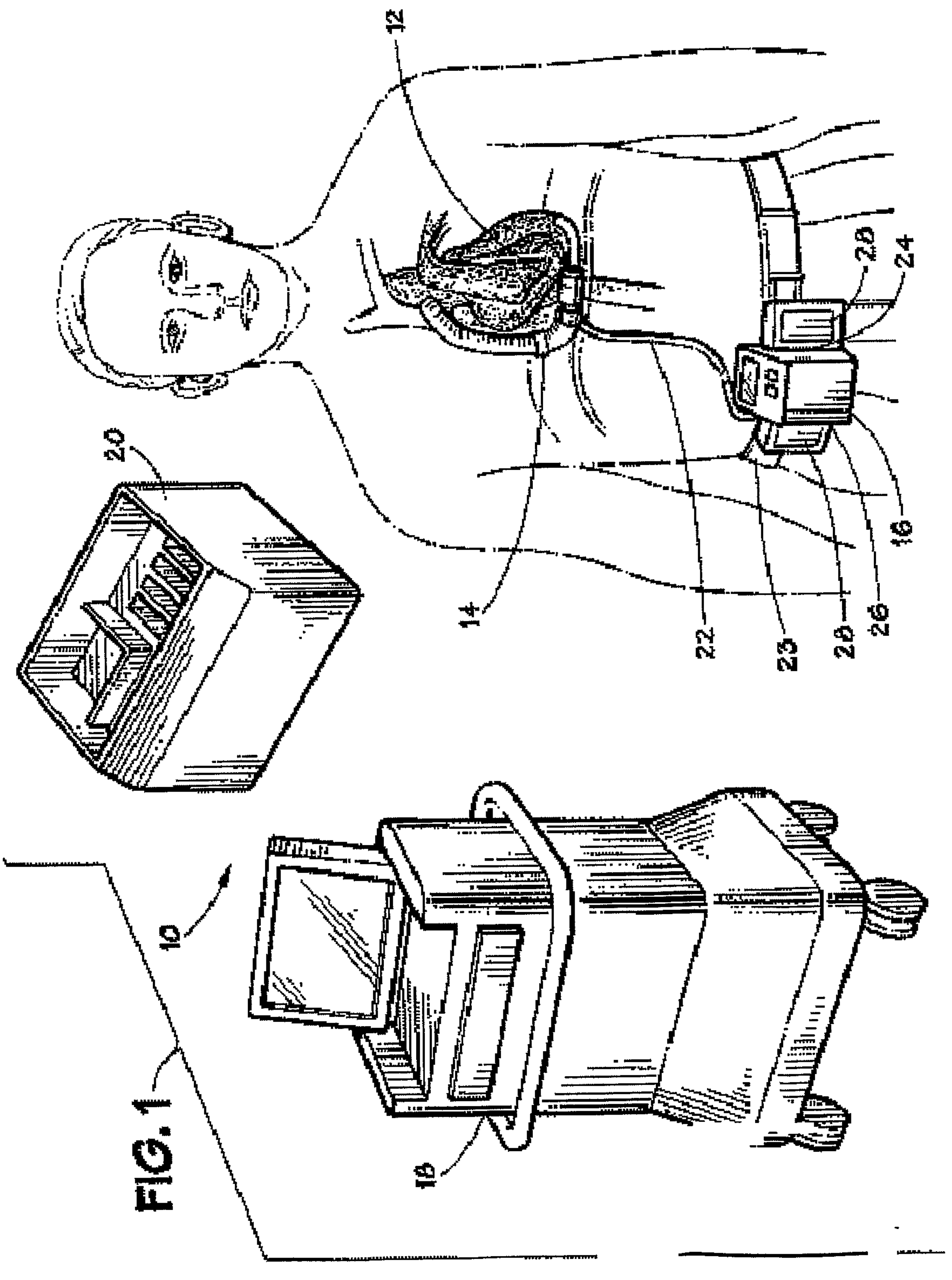

FIG. 1

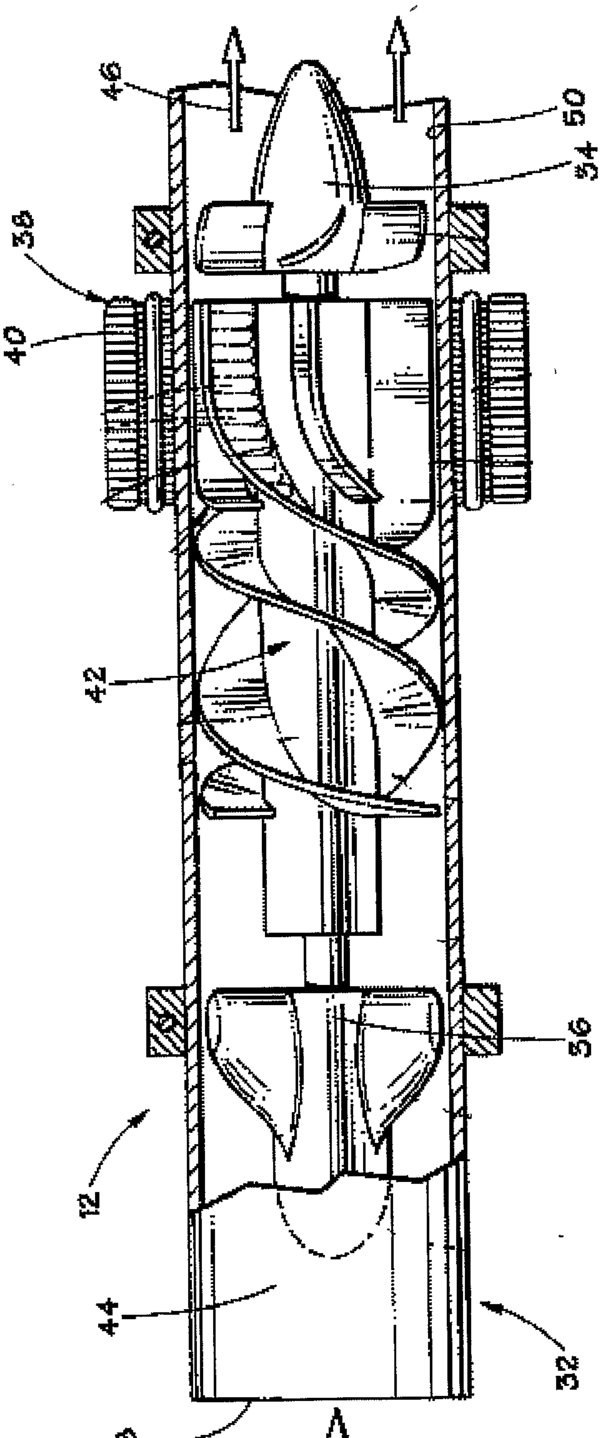

FIG. 2

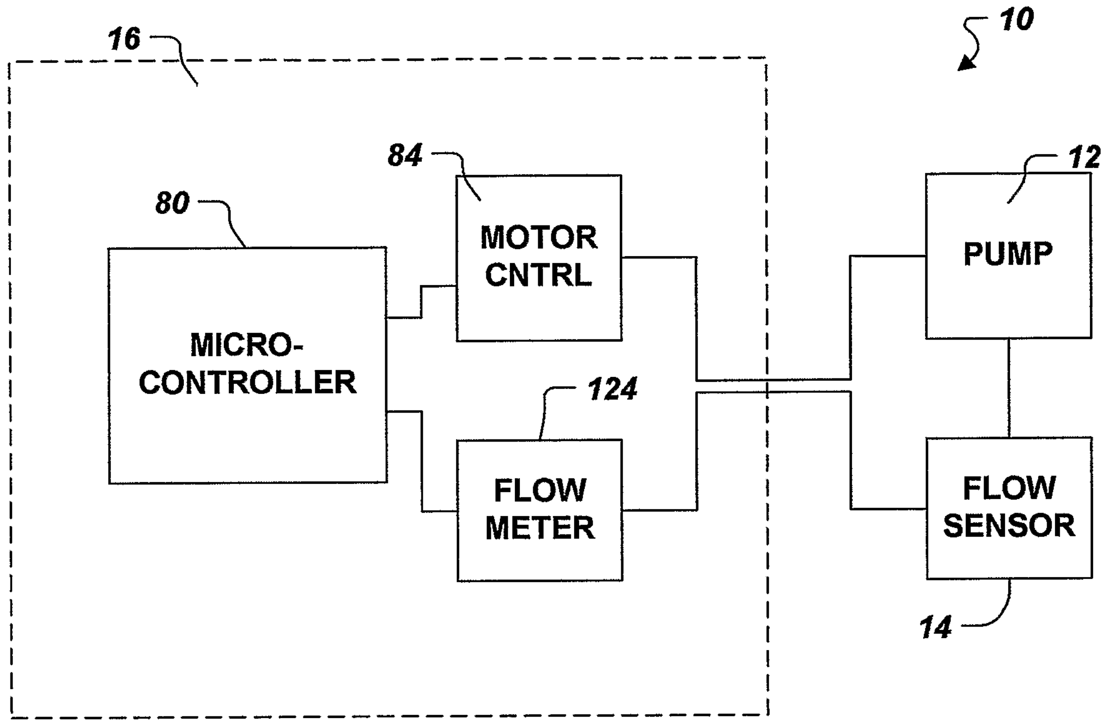
16
10
84
80
12
MOTOR
CNTRL
PUMP
MICRO-
CONTROLLER
124
FLOW
METER
FLOW
SENSOR
14

FIG. 3

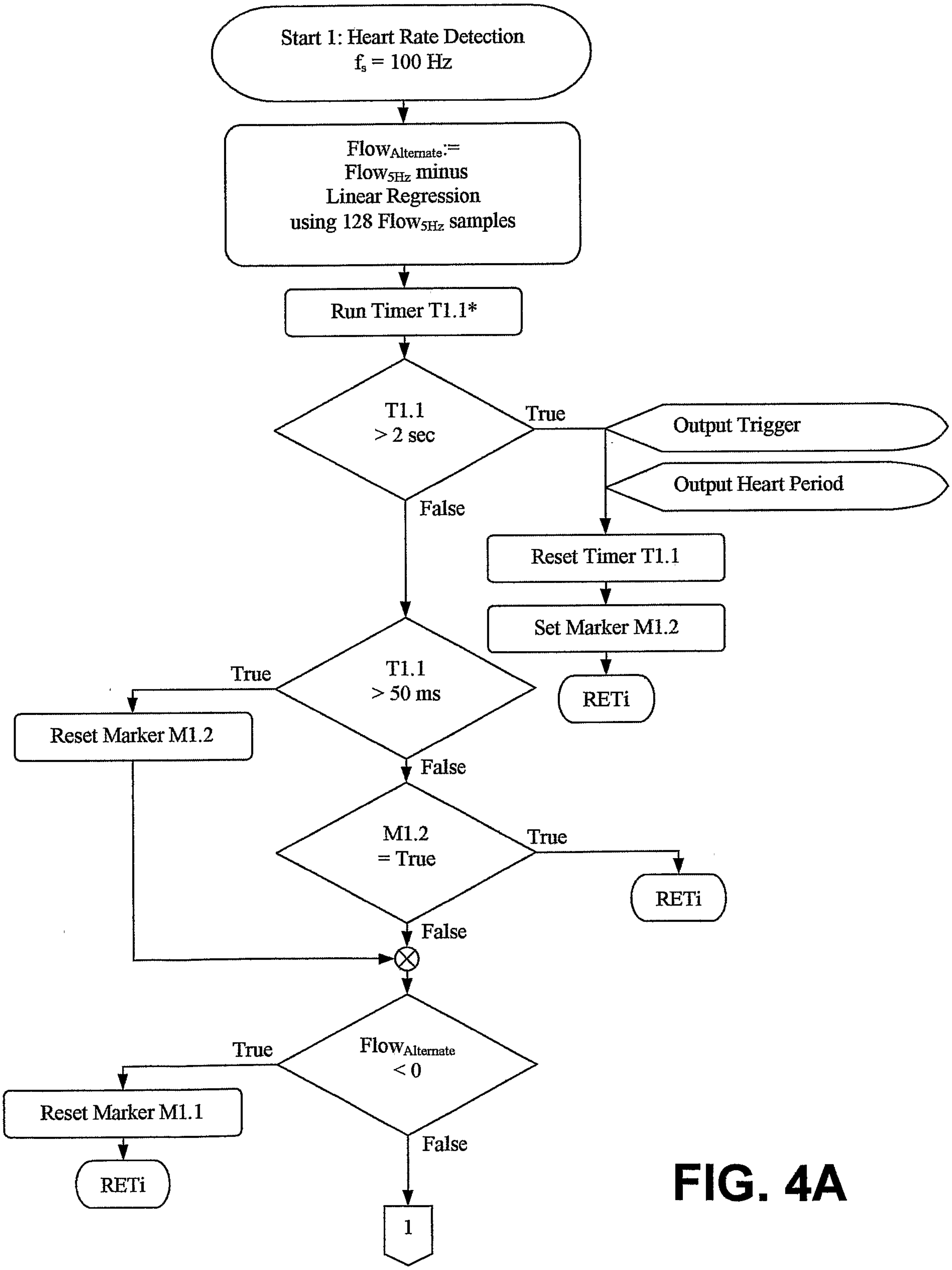
Start 1: Heart Rate Detection
f_s = 100 Hz
Flow_Alternate := Flow_5Hz minus Linear Regression using 128 Flow_5Hz samples
Run Timer T1.1*
T1.1 > 2 sec
True
False
Output Trigger
Output Heart Period
Reset Timer T1.1
Set Marker M1.2
RETi
T1.1 > 50 ms
True
False
Reset Marker M1.2
M1.2 = True
True
False
RETi
Flow_Alternate < 0
True
False
Reset Marker M1.1
RETi
1

FIG. 4A

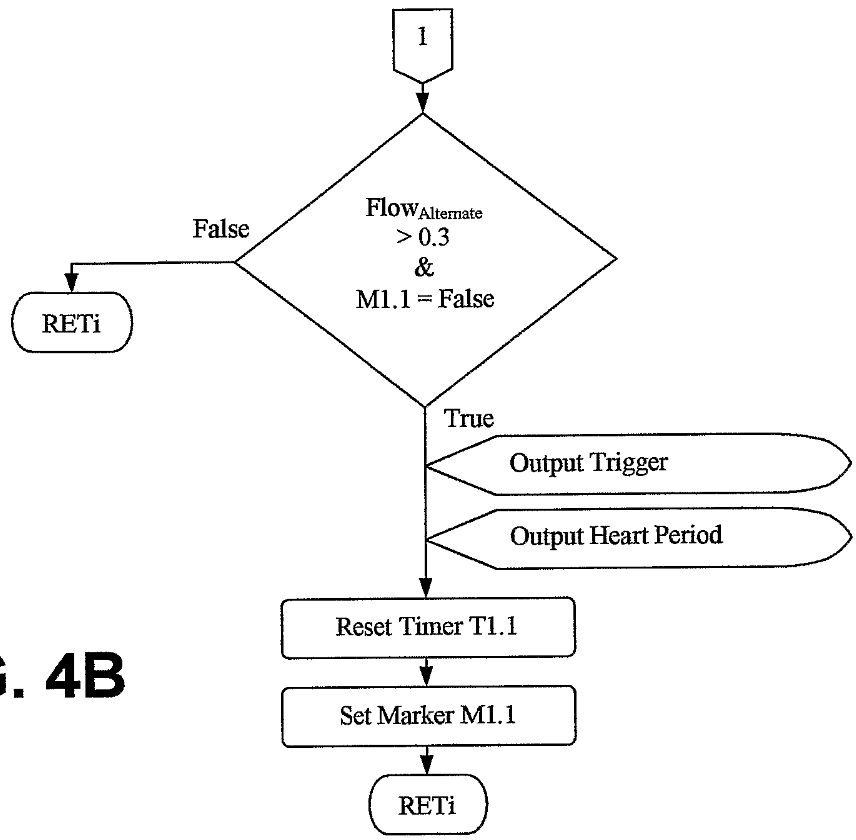
1
$Flow_{Alternate}$ > 0.3 & M1.1 = False
False
RETi
True
Output Trigger
Output Heart Period
Reset Timer T1.1
Set Marker M1.1
RETi

FIG. 4B

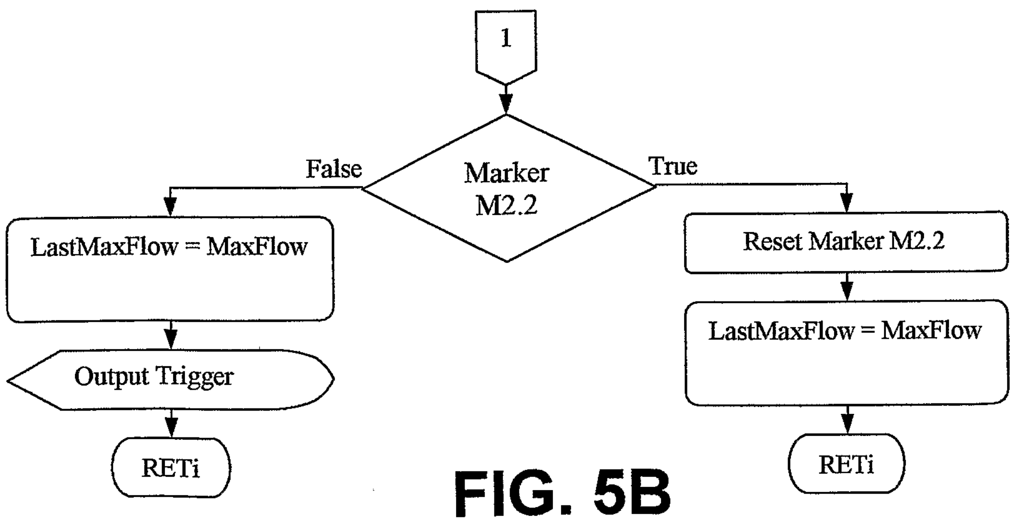
1
Marker M2.2
False
True
LastMaxFlow = MaxFlow
Output Trigger
RETi
Reset Marker M2.2
LastMaxFlow = MaxFlow
RETi

FIG. 5B

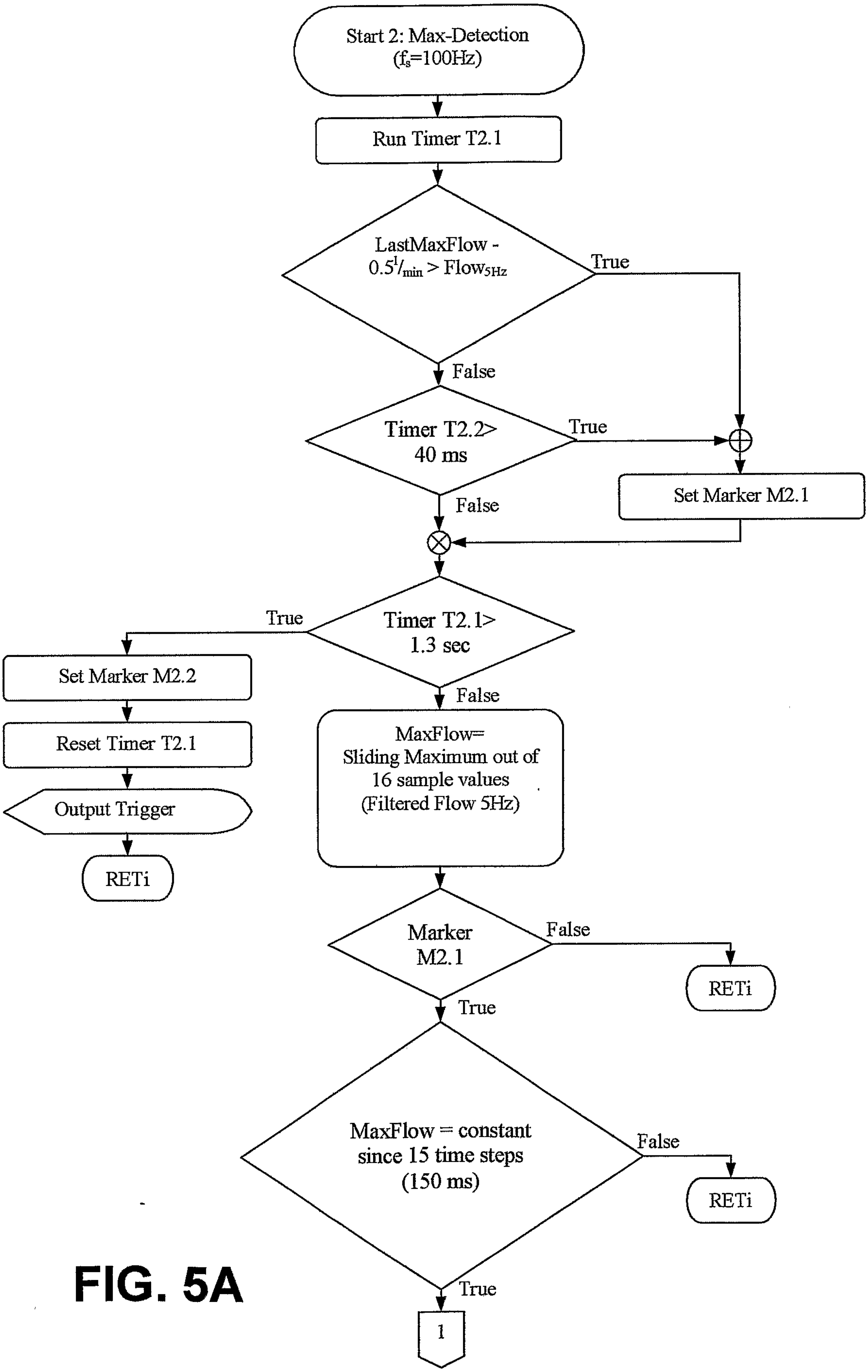
Start 2: Max-Detection
(f_s=100Hz)
Run Timer T2.1
LastMaxFlow - $0.5^{l}/_{min}$ > $Flow_{5Hz}$
True
False
Timer T2.2> 40 ms
True
False
Set Marker M2.1
Timer T2.1> 1.3 sec
True
False
Set Marker M2.2
Reset Timer T2.1
Output Trigger
RETi
MaxFlow= Sliding Maximum out of 16 sample values (Filtered Flow 5Hz)
Marker M2.1
False
True
RETi
MaxFlow = constant since 15 time steps (150 ms)
False
True
RETi
1

FIG. 5A

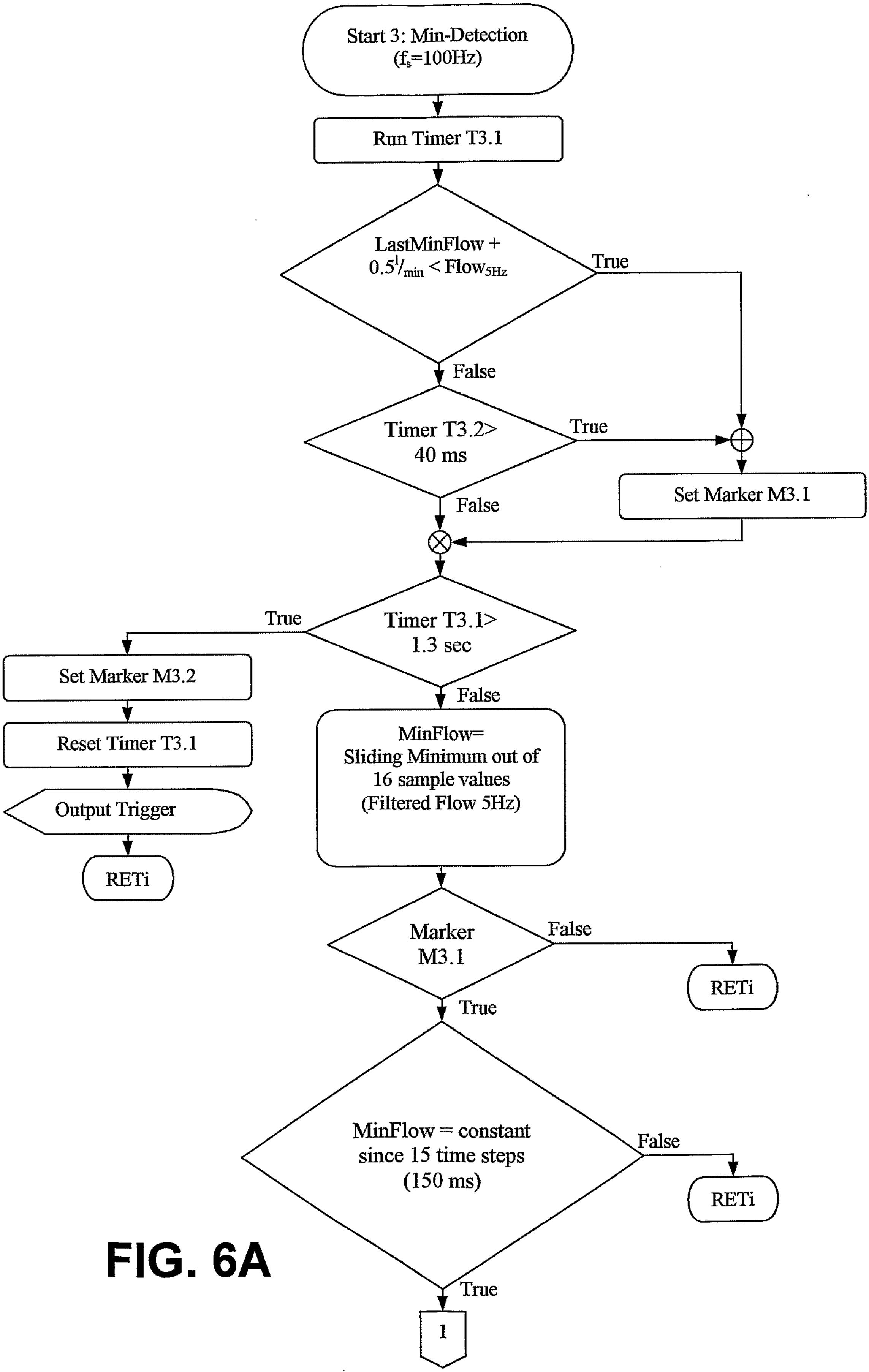
Start 3: Min-Detection
(f_s=100Hz)
Run Timer T3.1
LastMinFlow +
$0.5^{l}/_{min}$ < $Flow_{5Hz}$
True
False
Timer T3.2>
40 ms
True
Set Marker M3.1
False
Timer T3.1>
1.3 sec
True
Set Marker M3.2
Reset Timer T3.1
Output Trigger
RETi
False
MinFlow=
Sliding Minimum out of
16 sample values
(Filtered Flow 5Hz)
Marker
M3.1
False
RETi
True
MinFlow = constant
since 15 time steps
(150 ms)
False
RETi
True
1

FIG. 6A

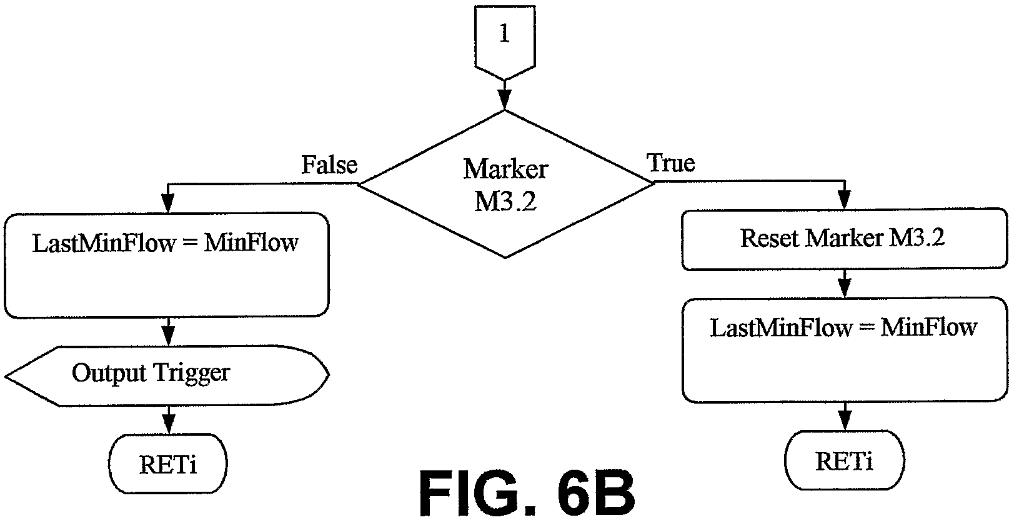
1
Marker
M3.2
False
True
LastMinFlow = MinFlow
Output Trigger
RETi
Reset Marker M3.2
LastMinFlow = MinFlow
RETi

FIG. 6B

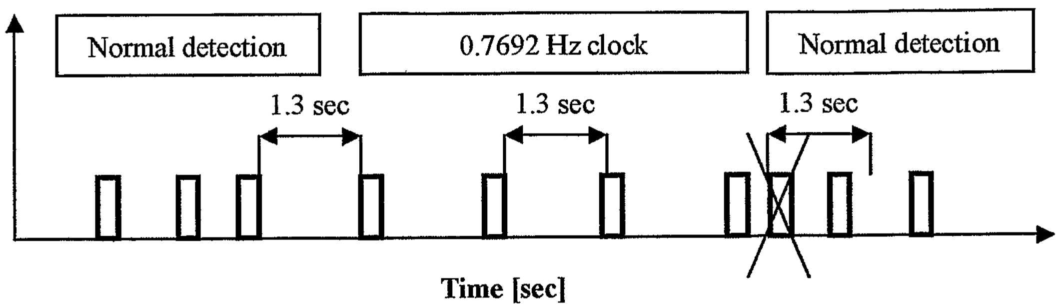
Normal detection
0.7692 Hz clock
Normal detection
1.3 sec
1.3 sec
1.3 sec
Time [sec]

FIG. 7

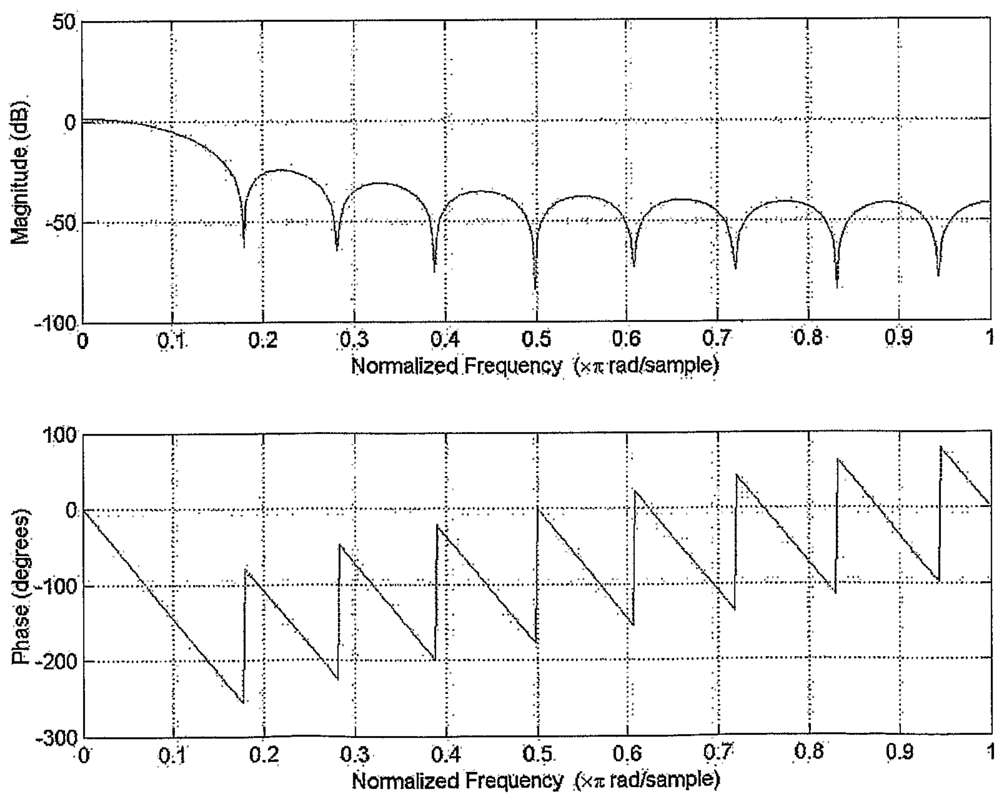
50
0
-50
-100
Magnitude (dB)
0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1
Normalized Frequency (×π rad/sample)
100
0
-100
-200
-300
Phase (degrees)
0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1
Normalized Frequency (×π rad/sample)

FIG. 8

14 sample values at a sample time of Ts = 10 ms.

Qz^{-13}	Qz^{-12}	Qz^{-11}	Qz^{-10}	Qz^{-9}	Qz^{-8}	Qz^{-7}	Qz^{-6}	Qz^{-5}	Qz^{-4}	Qz^{-3}	Qz^{-2}	Qz^{-1}	Q

$$Flow_{mean1} = \frac{Qz^{-6} + Qz^{-5} + Qz^{-4} + Qz^{-3} + Qz^{-2} + Qz^{-1} + Q}{7}$$

$$Flow_{mean2} = \frac{Qz^{-13} + Qz^{-12} + Qz^{-11} + Qz^{-10} + Qz^{-9} + Qz^{-8} + Qz^{-7}}{7}$$

$$Flow_{Derivation} = \frac{(Flow_{mean1} - Flow_{mean2})}{7T_S}$$

FIG. 9

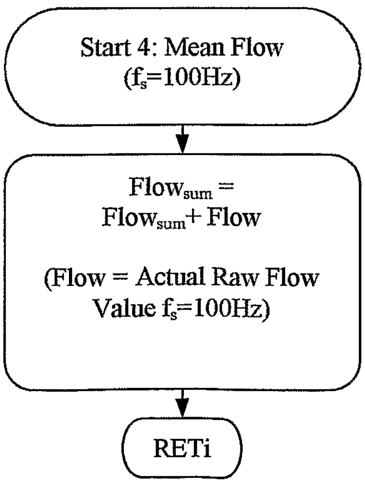

FIG. 10A

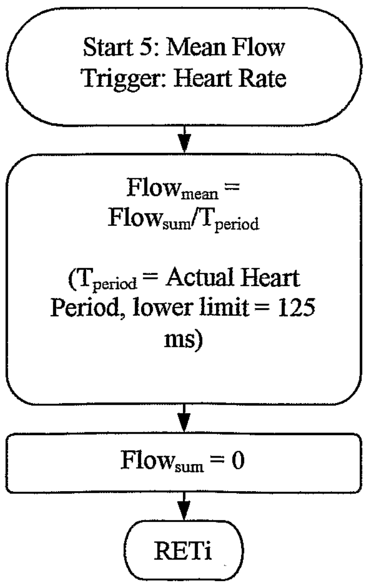

FIG. 10B

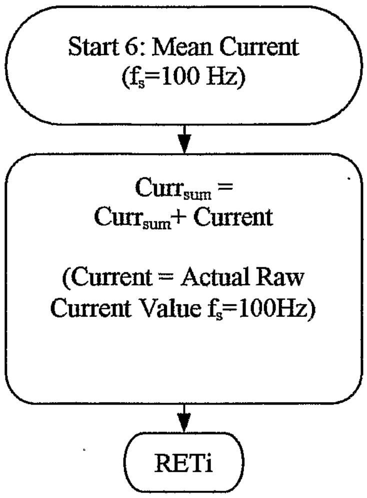

FIG. 11A

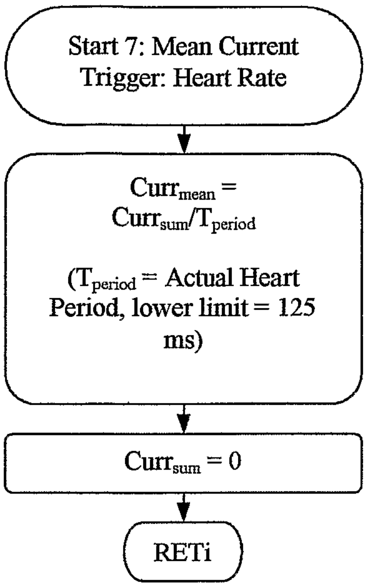

FIG. 11B

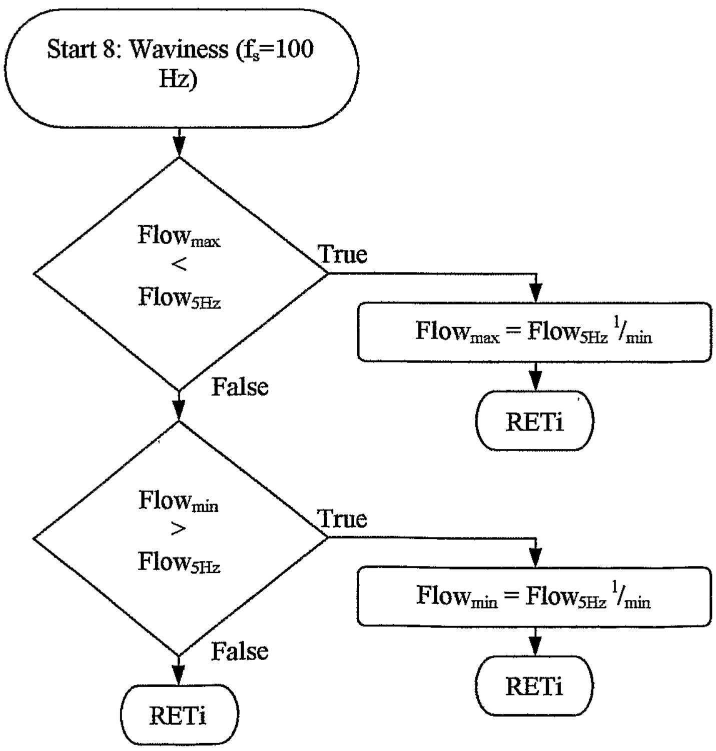

FIG. 12A

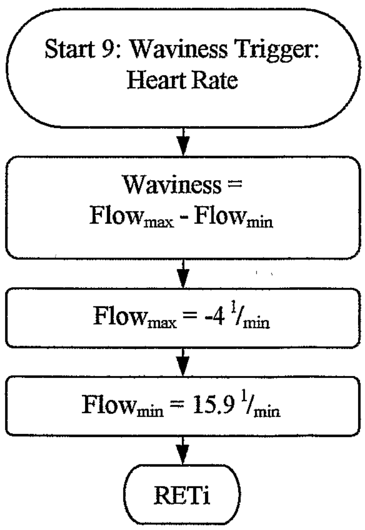

FIG. 12B

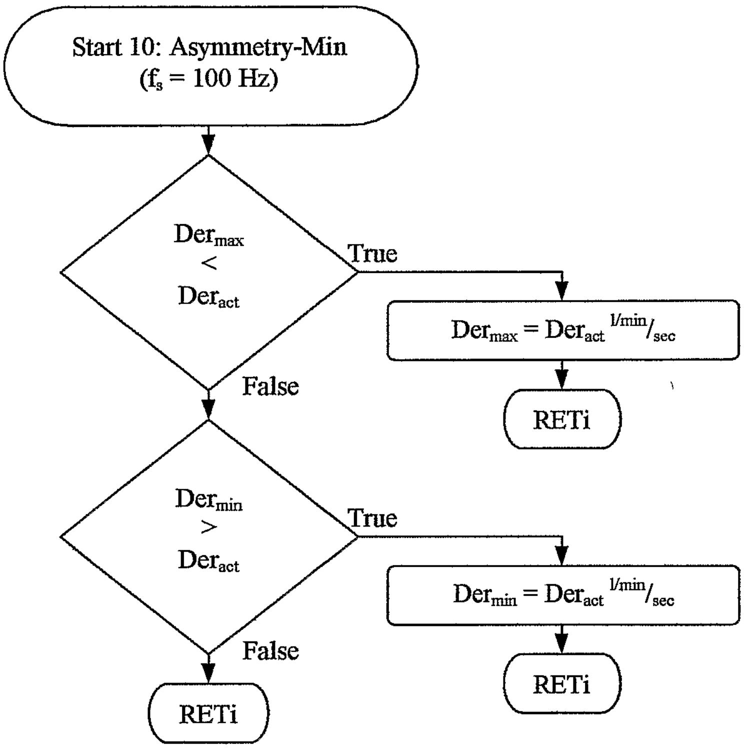

FIG. 13A

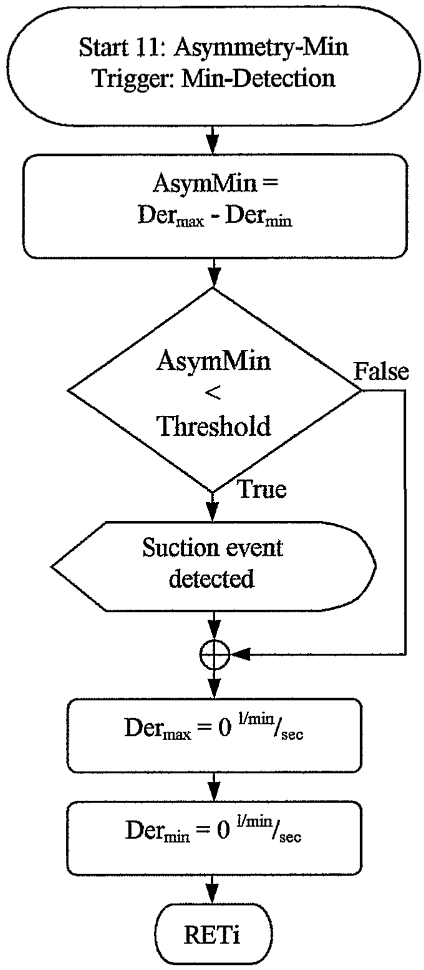

FIG. 13B

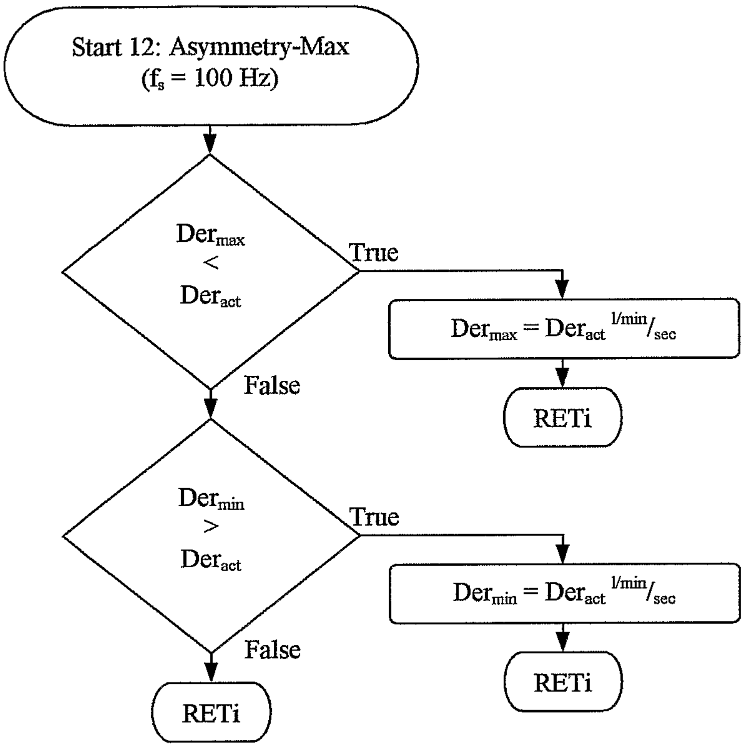

FIG. 14A

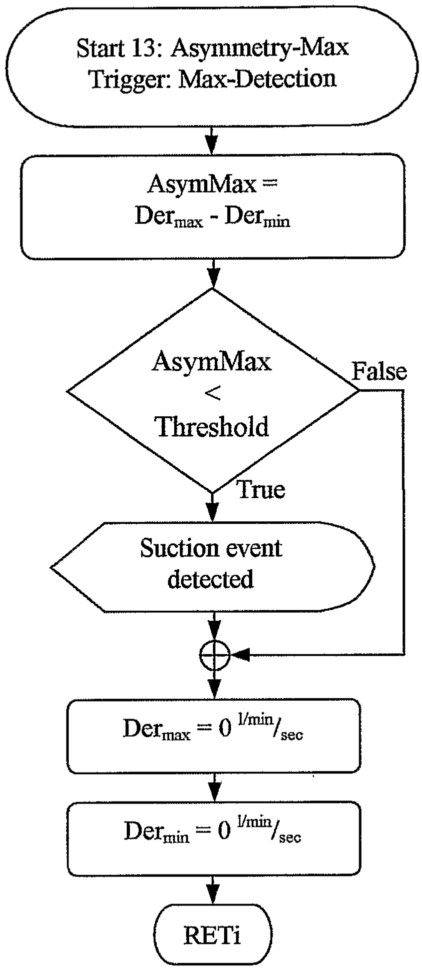

FIG. 14B

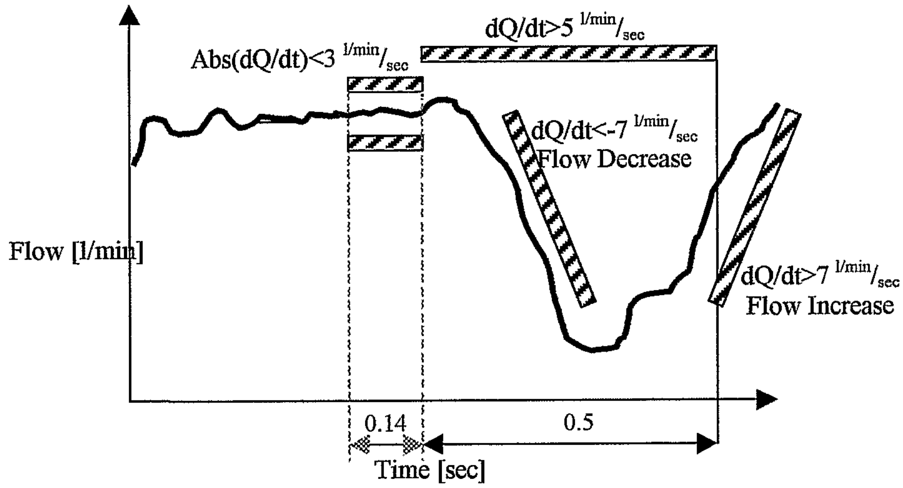
Abs(dQ/dt)<3 l/min/sec
dQ/dt>5 l/min/sec
dQ/dt<-7 l/min/sec
Flow Decrease
Flow [l/min]
dQ/dt>7 l/min/sec
Flow Increase
0.14
0.5
Time [sec]

FIG. 15

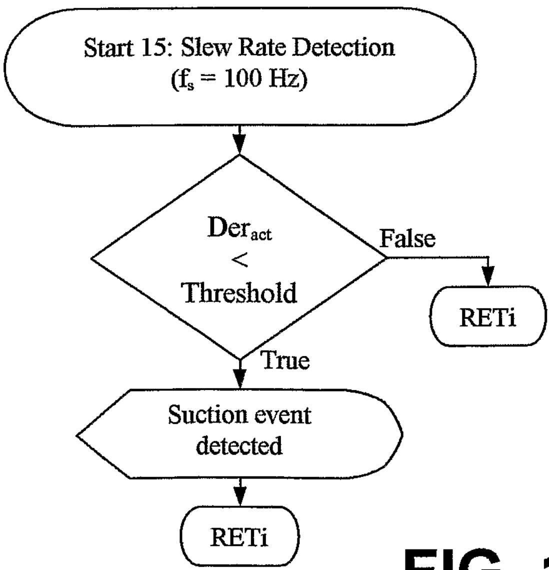
Start 15: Slew Rate Detection
(fs = 100 Hz)
Der act
<
Threshold
False
RETi
True
Suction event
detected
RETi

FIG. 17

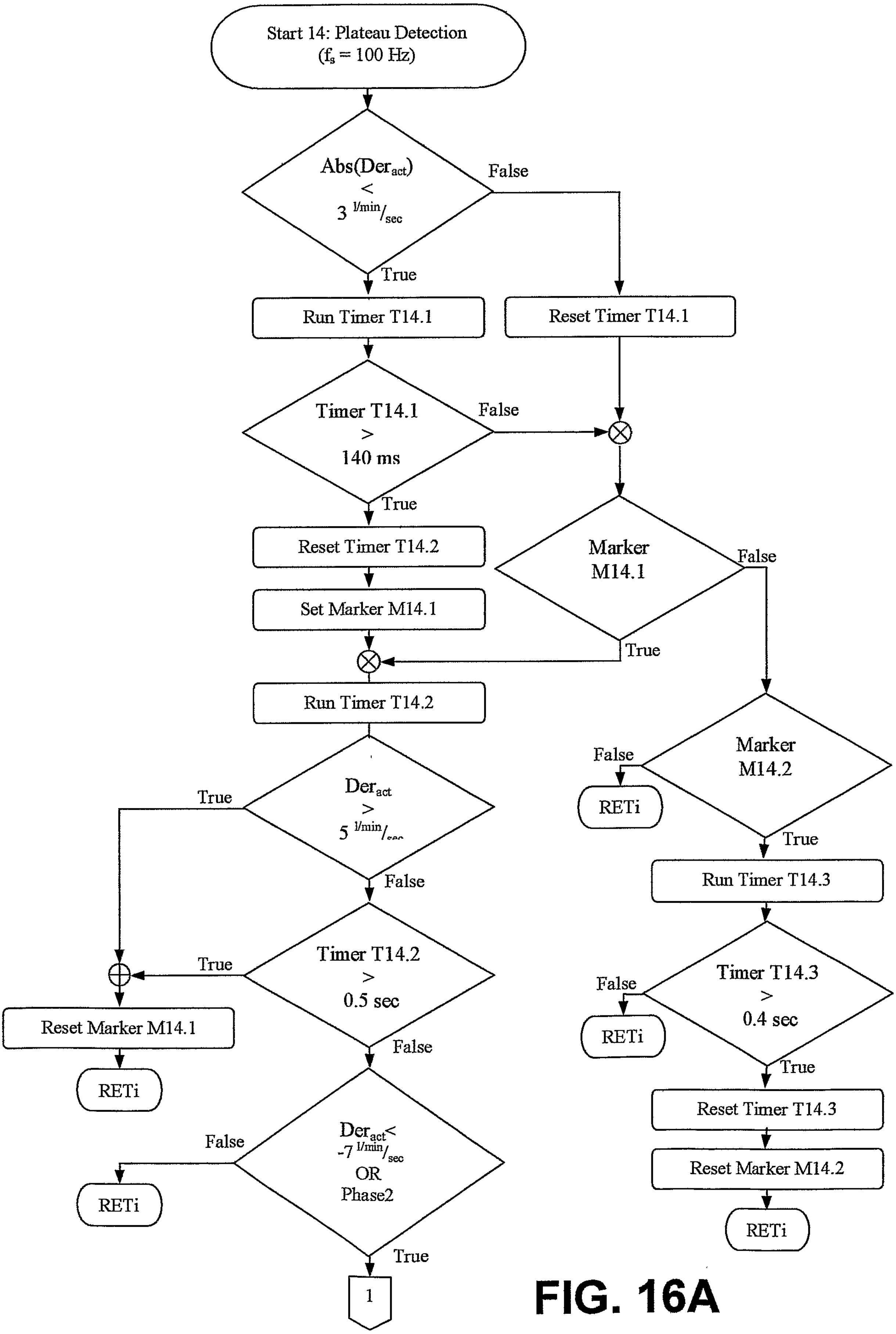
Start 14: Plateau Detection
(f_s = 100 Hz)
Abs(Der_{act}) < 3 $^{l/min}/_{sec}$
False
True
Run Timer T14.1
Reset Timer T14.1
Timer T14.1 > 140 ms
False
True
Reset Timer T14.2
Set Marker M14.1
Marker M14.1
False
True
Run Timer T14.2
Marker M14.2
False
RETi
True
Der_{act} > 5 $^{l/min}/_{sec}$
True
False
Run Timer T14.3
Timer T14.2 > 0.5 sec
True
False
Timer T14.3 > 0.4 sec
False
RETi
True
Reset Marker M14.1
RETi
Reset Timer T14.3
Reset Marker M14.2
RETi
Der_{act}< -7 $^{l/min}/_{sec}$ OR Phase2
False
RETi
True
1

FIG. 16A

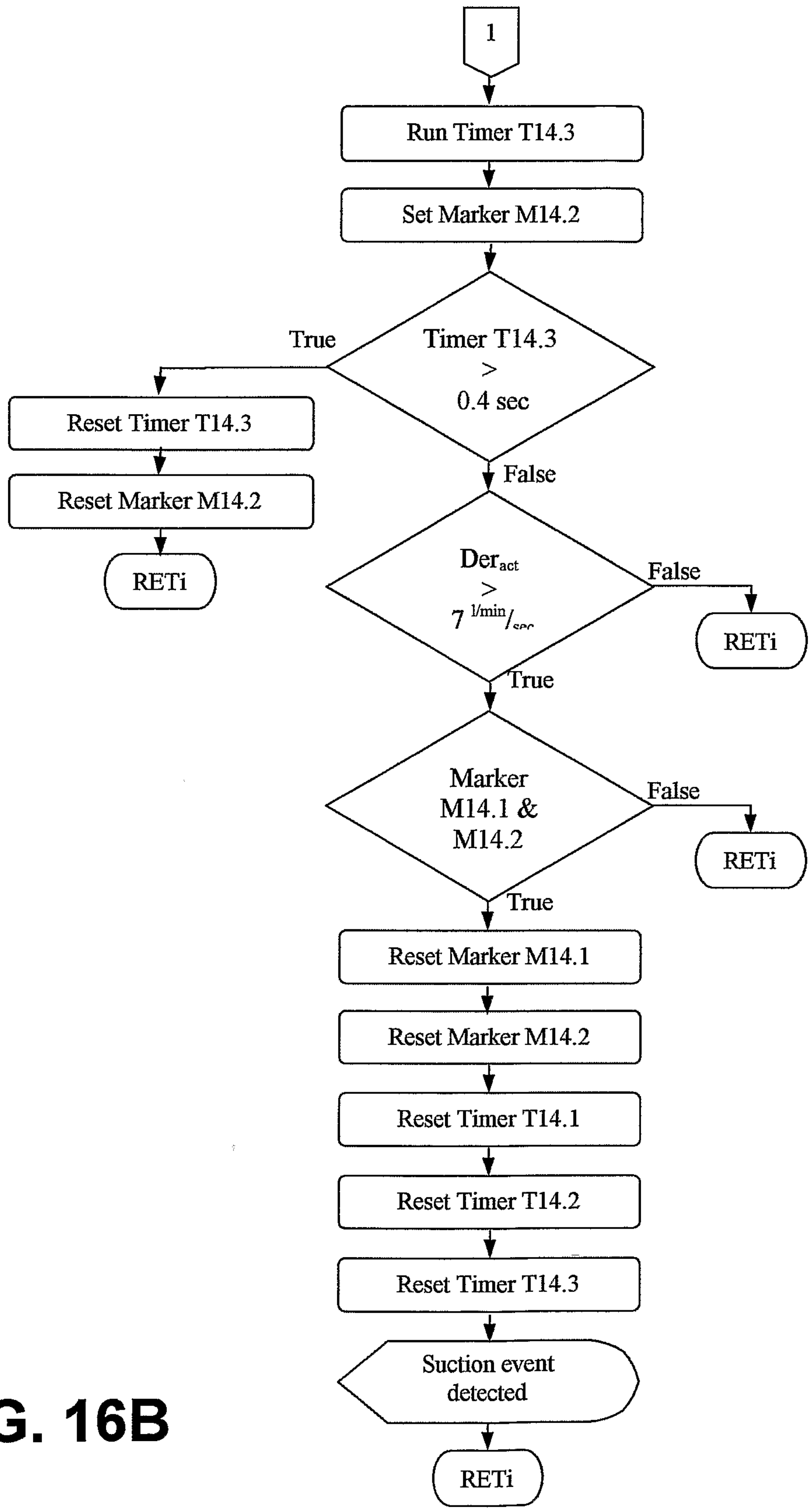
1
Run Timer T14.3
Set Marker M14.2
Timer T14.3 > 0.4 sec
True
Reset Timer T14.3
Reset Marker M14.2
RETi
False
Der act > 7 1/min/sec
False
RETi
True
Marker M14.1 & M14.2
False
RETi
True
Reset Marker M14.1
Reset Marker M14.2
Reset Timer T14.1
Reset Timer T14.2
Reset Timer T14.3
Suction event detected
RETi

FIG. 16B

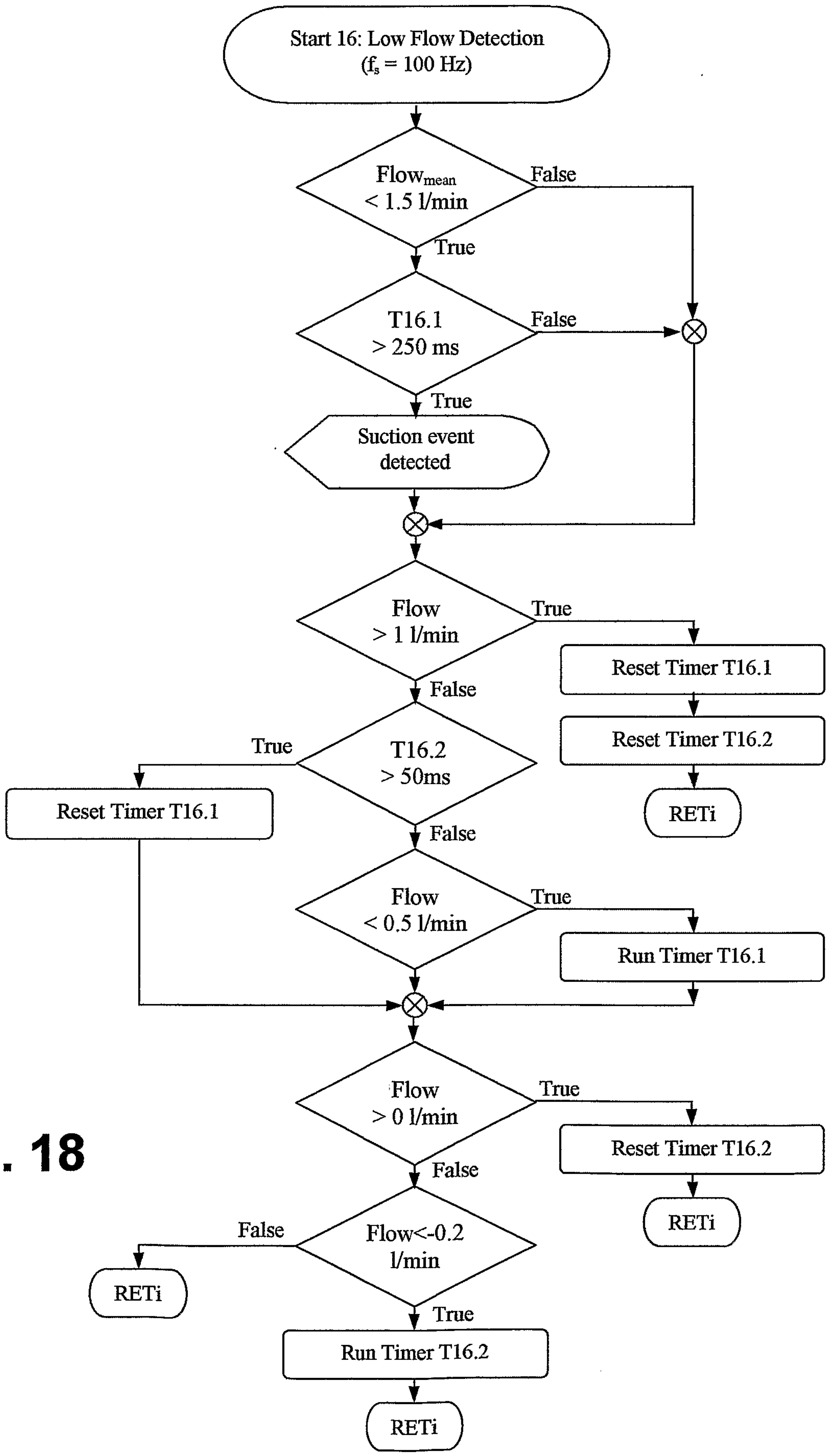
Start 16: Low Flow Detection
(f_s = 100 Hz)
$Flow_{mean}$ < 1.5 l/min
False
True
T16.1 > 250 ms
False
True
Suction event detected
Flow > 1 l/min
True
Reset Timer T16.1
Reset Timer T16.2
RETi
False
T16.2 > 50ms
True
Reset Timer T16.1
False
Flow < 0.5 l/min
True
Run Timer T16.1
Flow > 0 l/min
True
Reset Timer T16.2
RETi
False
Flow<-0.2 l/min
False
RETi
True
Run Timer T16.2
RETi

FIG. 18

$$[(Q_{mean}-Q_{minimum})-(Q_{maximum}-Q_{mean})] = (2Q_{mean}-Q_{minimum}-Q_{maximum}) < \text{Threshold } [^{1}/_{min}]$$

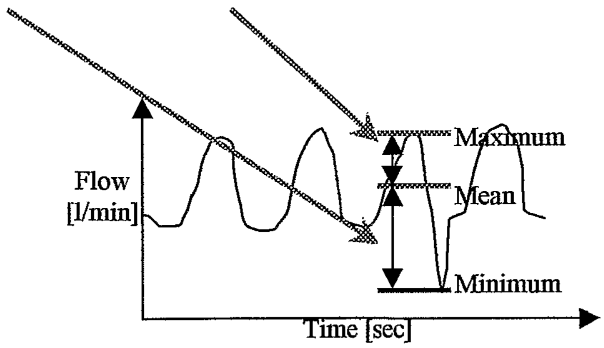

FIG. 19

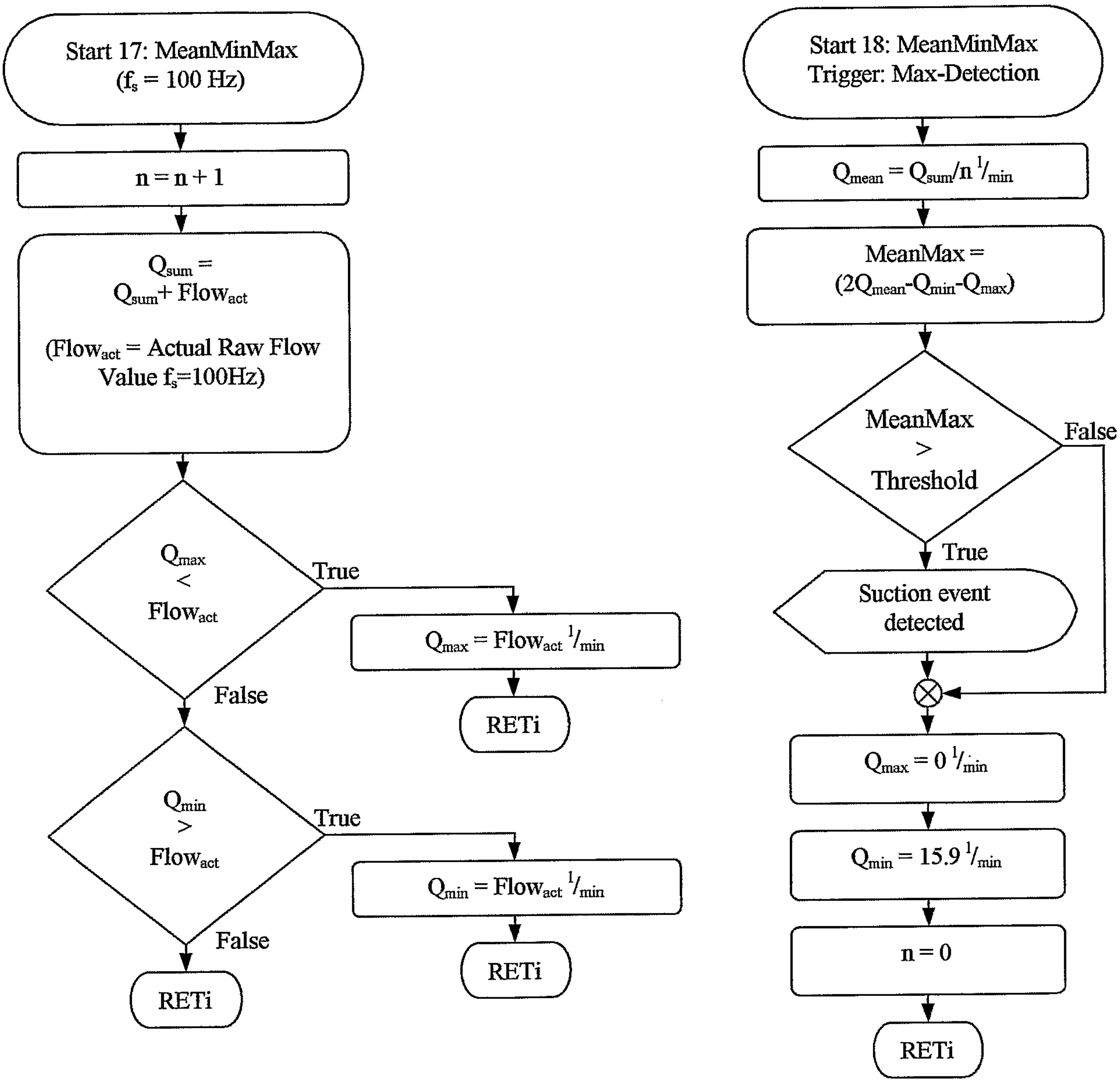
Start 17: MeanMinMax
(f_s = 100 Hz)
n = n + 1
Q_{sum} =
Q_{sum}+ $Flow_{act}$
($Flow_{act}$ = Actual Raw Flow
Value f_s=100Hz)
Q_{max} < $Flow_{act}$
True
$Q_{max} = Flow_{act}$ $^1/_{min}$
RETi
False
Q_{min} > $Flow_{act}$
True
$Q_{min} = Flow_{act}$ $^1/_{min}$
RETi
False
RETi
Start 18: MeanMinMax
Trigger: Max-Detection
$Q_{mean} = Q_{sum}/n$ $^1/_{min}$
MeanMax =
($2Q_{mean}-Q_{min}-Q_{max}$)
MeanMax > Threshold
False
True
Suction event
detected
$Q_{max} = 0$ $^1/_{min}$
$Q_{min} = 15.9$ $^1/_{min}$
n = 0
RETi

FIG. 20

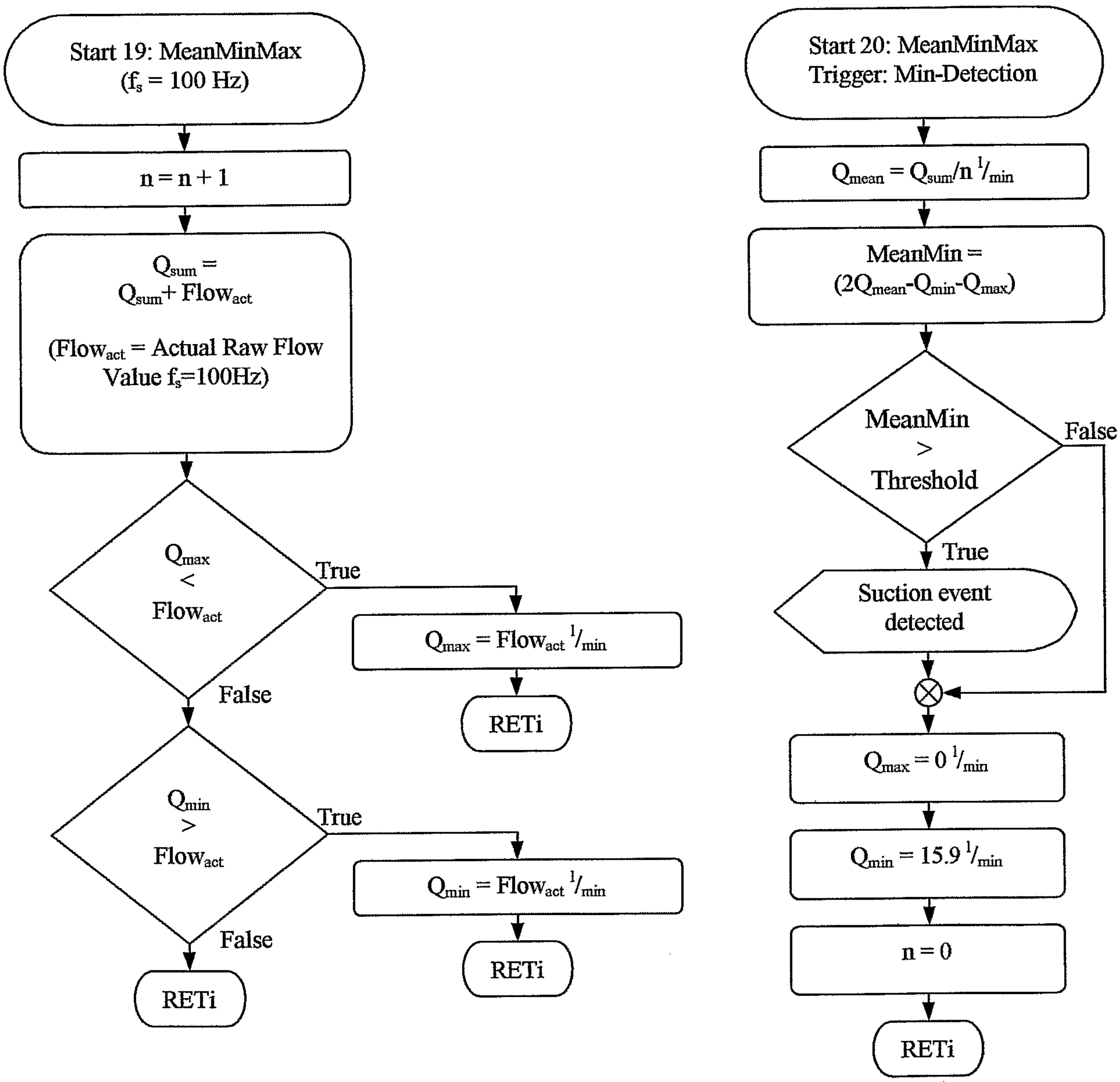
Start 19: MeanMinMax
(f_s = 100 Hz)
n = n + 1
Q_{sum} =
Q_{sum}+ $Flow_{act}$
($Flow_{act}$ = Actual Raw Flow
Value f_s=100Hz)
Q_{max}
<
$Flow_{act}$
True
False
$Q_{max} = Flow_{act}$ $^{1}/_{min}$
RETi
Q_{min}
>
$Flow_{act}$
True
False
$Q_{min} = Flow_{act}$ $^{1}/_{min}$
RETi
RETi
Start 20: MeanMinMax
Trigger: Min-Detection
$Q_{mean} = Q_{sum}/n$ $^{1}/_{min}$
MeanMin =
($2Q_{mean}$-Q_{min}-Q_{max})
MeanMin
>
Threshold
False
True
Suction event
detected
Q_{max} = 0 $^{1}/_{min}$
Q_{min} = 15.9 $^{1}/_{min}$
n = 0
RETi

FIG. 21

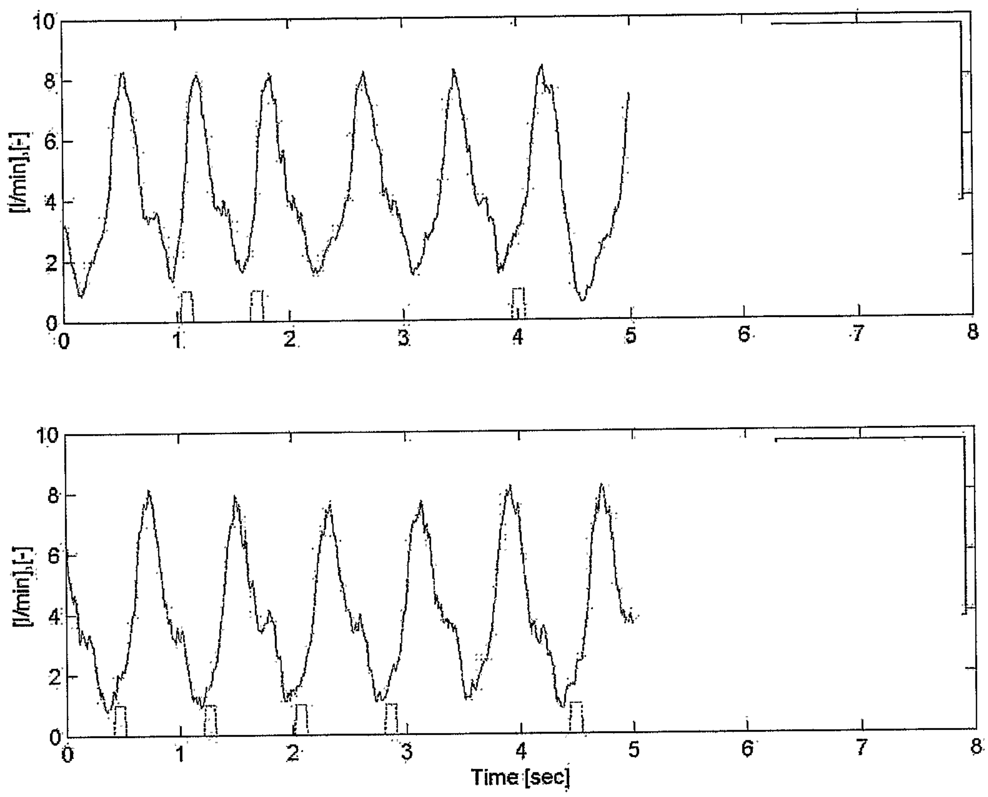

FIG. 22

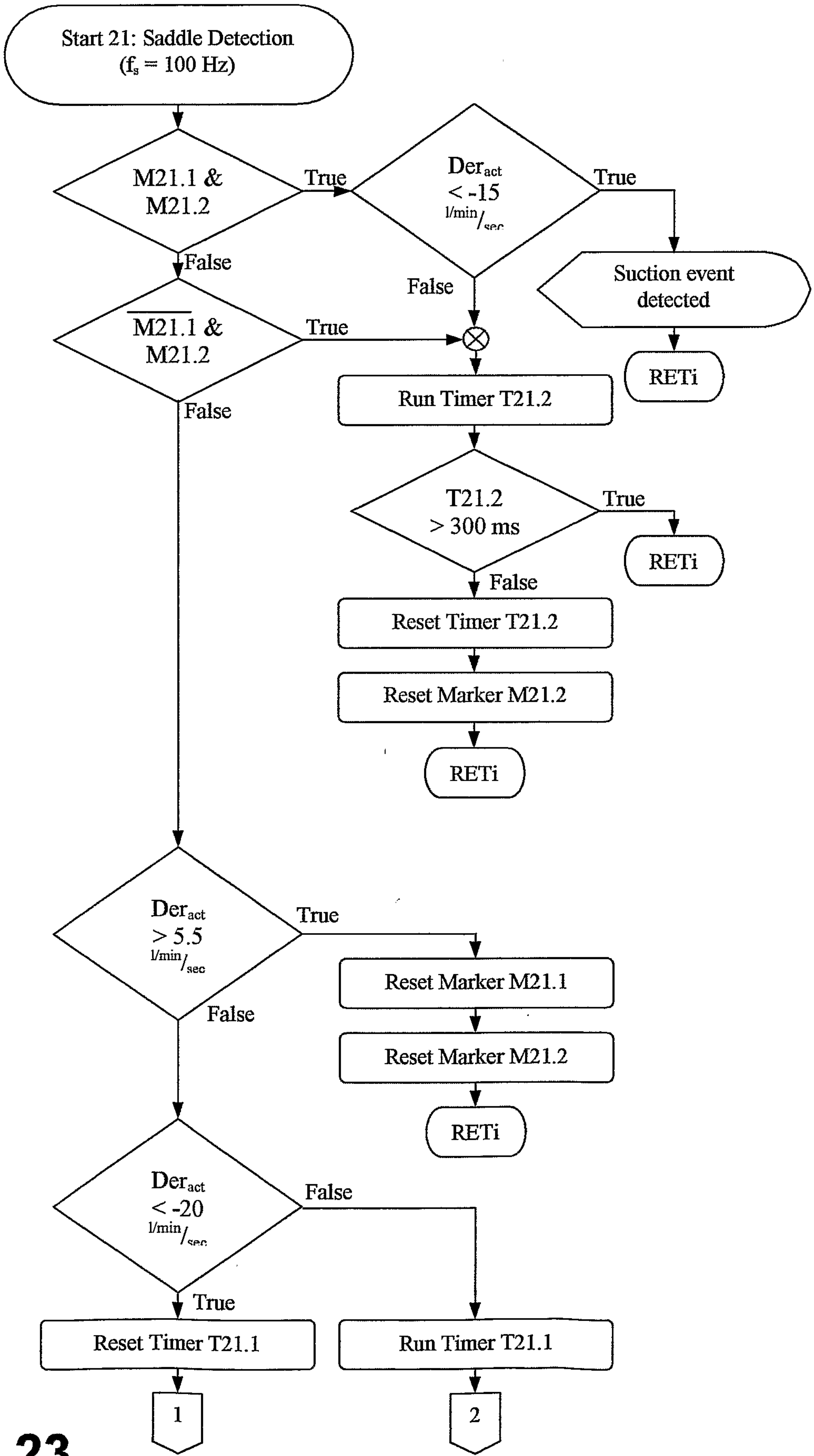
Start 21: Saddle Detection
(f_s = 100 Hz)
M21.1 &
M21.2
True
Der_{act}
< -15
l/min/sec
True
Suction event
detected
RETi
False
False
$\overline{M21.1}$ &
M21.2
True
False
Run Timer T21.2
T21.2
> 300 ms
True
RETi
False
Reset Timer T21.2
Reset Marker M21.2
RETi
Der_{act}
> 5.5
l/min/sec
True
False
Reset Marker M21.1
Reset Marker M21.2
RETi
Der_{act}
< -20
l/min/sec
False
True
Reset Timer T21.1
Run Timer T21.1
1
2

FIG. 23

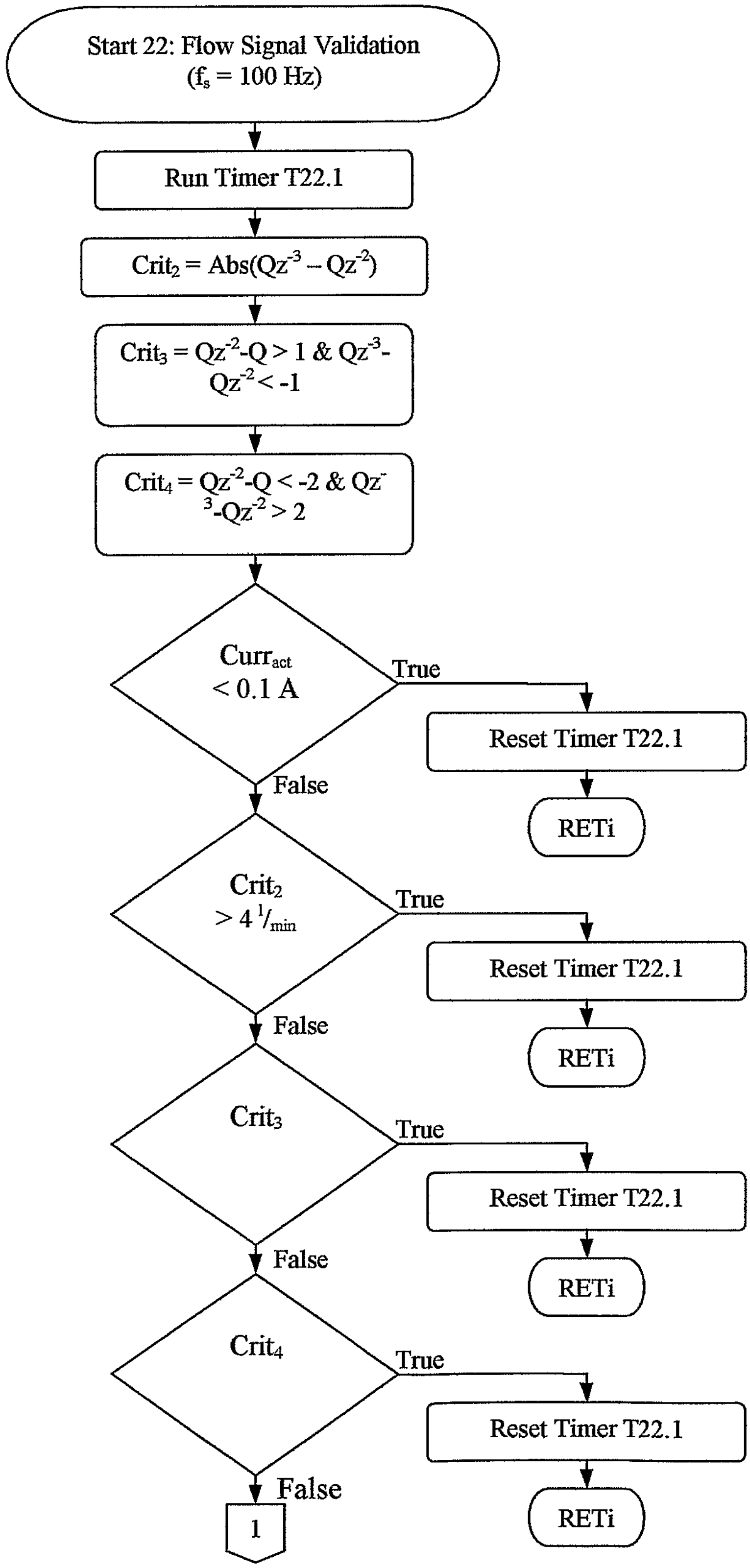
Start 22: Flow Signal Validation
(f_s = 100 Hz)
Run Timer T22.1
$Crit_2 = Abs(Qz^{-3} - Qz^{-2})$
$Crit_3 = Qz^{-2}-Q > 1$ & $Qz^{-3}-Qz^{-2} < -1$
$Crit_4 = Qz^{-2}-Q < -2$ & $Qz^{-3}-Qz^{-2} > 2$
$Curr_{act}$ < 0.1 A
True
Reset Timer T22.1
RETi
False
$Crit_2$ > 4 $^{l}/_{min}$
True
Reset Timer T22.1
RETi
False
$Crit_3$
True
Reset Timer T22.1
RETi
False
$Crit_4$
True
Reset Timer T22.1
RETi
False
1

FIG. 24A

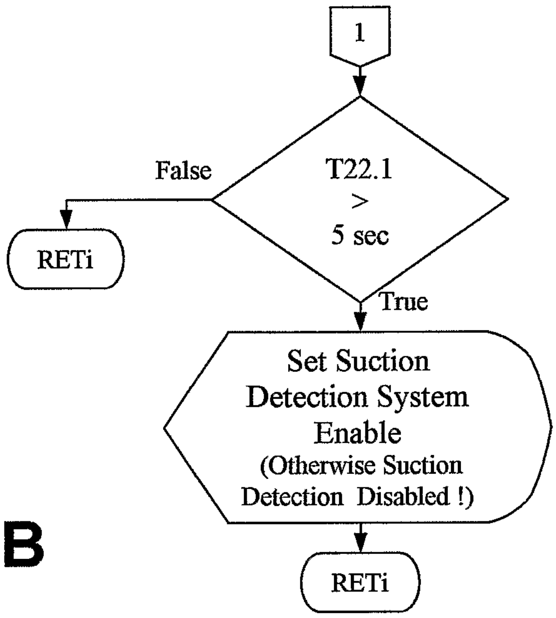
1
T22.1
>
5 sec
False
RETi
True
Set Suction
Detection System
Enable
(Otherwise Suction
Detection Disabled !)
RETi

FIG. 24B

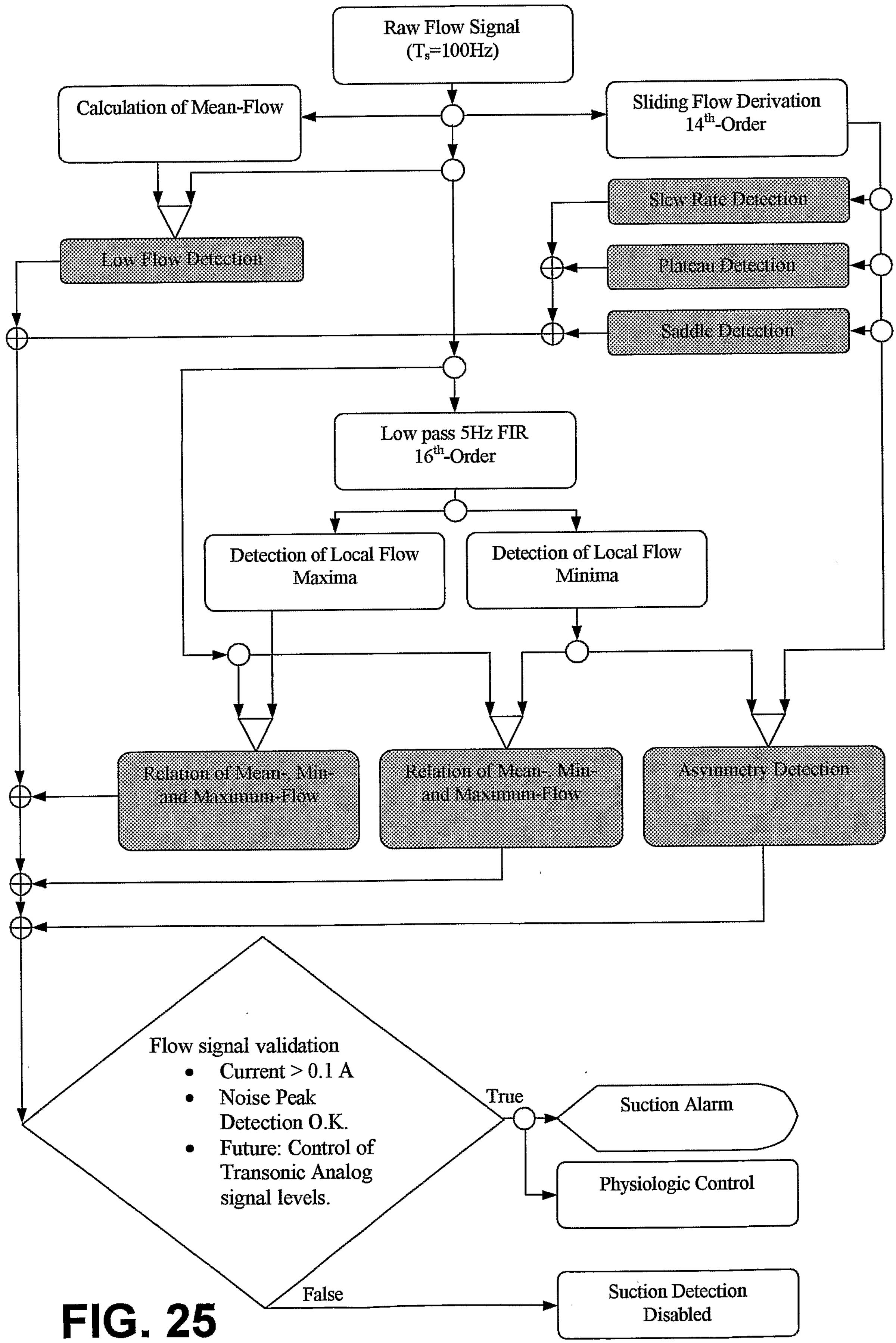
Raw Flow Signal
(Ts=100Hz)
Calculation of Mean-Flow
Sliding Flow Derivation
14th-Order
Slew Rate Detection
Low Flow Detection
Plateau Detection
Saddle Detection
Low pass 5Hz FIR
16th-Order
Detection of Local Flow
Maxima
Detection of Local Flow
Minima
Relation of Mean-, Min-
and Maximum-Flow
Relation of Mean-, Min-
and Maximum-Flow
Asymmetry Detection
Flow signal validation
Current > 0.1 A
Noise Peak
Detection O.K.
Future: Control of
Transonic Analog
signal levels.
True
Suction Alarm
Physiologic Control
False
Suction Detection
Disabled

FIG. 25