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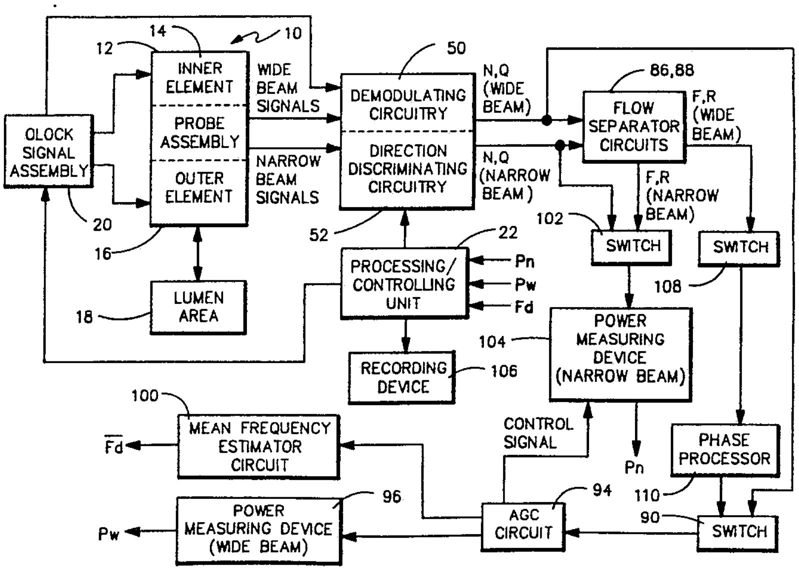

(57) Abstract

A non-invasive ultrasonic volume blood measurement system includes a transducer probe assembly (10) having an inner and a concentric outer element (14, 16). Both are used to insonify a lumen area and to generate received signals representative of wide and narrow beams. The signals are processed simultaneously to produce respective Doppler power spectrums. Phase quadrature signals are generated for determining flow direction, and an AGC circuit (94) provides output signals controlling the amplitude of both spectrums for accurate computation of beam power ratio. A mean frequency estimator circuit (100) determines flow velocity at the lumen area, and a recording thereof is observed by the operator to ensure correct placement of the probe assembly (10) for insonifying a desired lumen area. Thereafter, a processing/controlling unit (22) determines volume blood flow by multiplying the determined flow velocity by the ratio of the obtained powers in the wide and narrow beams.

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METHOD AND APPARATUS FOR MEASURING VOLUME FLUID FLOW

Field of the Invention

The present invention relates to systems for determining volume fluid flow and, in particular, to a measuring apparatus that determines volume blood flow in a non-invasive manner.

Background Information

The monitoring of volume blood flow through a vessel or other conduit of a patient is important for a number of reasons. During surgery, it is beneficial to monitor blood flow of the patient, among other vital signs that are monitored, to enhance the safety of the patient. Cardiovascular disorders can be better diagnosed and assessed through observation and study of volume blood flow. Restricted volume blood flow, including the degree thereof, is indicative of some form of cardiovascular disease. Flow measurements are also important when there has been a loss of blood and when the body has been subject or exposed to infection, metabolic disease, and unwanted drug/anesthetic effects.

Techniques have been previously devised for measuring volume blood flow. Traditional methods include invasive steps in which there is some disruption or alteration of the vascular system to be measured. Invasive approaches are unsuitable for a variety of reasons, including patient discomfort, greater risk because of the invasive steps that are required, and the need to use sterilized and expensive, non-reusable medical devices, such as catheters.

To overcome the drawbacks associated with invasive techniques, non-invasive methods have been advanced. These systems typically rely on the use of ultrasound and Doppler techniques. Basically, the velocity of the blood flow through a lumen is determined and that is multiplied by the cross-sectional or projected area of the lumen at the point of interest to determine volume blood flow.

A number of different approaches have been developed or proposed for determining volume blood flow. In U.S. Patent No. 4,067,236 to Hottinger, issued January 10, 1978, and entitled "Method and System for Unambiguous Measurement of Volume Flow," a Doppler system is disclosed in which flow velocity is determined as a function of the centroid or first moment of the Doppler power spectrum. In one embodiment disclosed in this patent, the lumen projected area is found using the ratios of returned Doppler power from two transducer elements. Circuitry is also described for providing information relating to the direction of blood flow. U.S. Patent No. 4,431,936 to Fu et al., issued February 14, 1984, and entitled "Transducer Structure for Generating Uniform and Focused Ultrasonic Beams and Applications Thereof" describes a transducer arrangement that, in one embodiment, includes outer and inner array elements for use in generating a wide beam and a narrow beam of ultrasonic energy. The Doppler information returning from the vessel of interest is used in determining volume blood flow. Another method for measuring flow volume that relies on a pair of transducer elements is found in U.S. Patent No. 3,977,247 to Hassler, issued August 31, 1976, and entitled "Arrangement for the Measurement of the Flow Volume of Flowing Media." The Hassler patent determines the lumen area of interest by using Doppler power associated with generated wide and narrow beams. The system disclosed in this patent also includes an indicator for displaying Doppler power signals from either the wide or narrow beam at any one time so that the highest intensity Doppler signal can be observed indicating that the narrower beam is passing through the blood vessel at the cross-sectional middle thereof. Further systems for measuring volume fluid flow using Doppler information are U.S. Patent No. 4,062,237 to Fox, issued December 13, 1977, and entitled "Cross Beam Ultrasonic Flowmeter," U.S. Patent No. 3,554,030 to Peronneau, issued

January 12, 1971, and entitled "Recording Ultrasonic Flowmeter for Blood Vessels," and U.S. Patent No. 3,498,290 to Shaw et al., issued March 3, 1970, and entitled "Pulsed Doppler Volumetric Blood Flowmeter." These patents reveal various circuit elements and arrangements thereof for processing the received Doppler input including the use of multiplying circuits, band pass filters, amplitude limiters, and range gating circuitry. Another apparatus for measuring blood flow velocity is described in U.S. Patent No. 4,593,700 to Hayakawi et al., issued June 10, 1986, and entitled "Ultrasonic Wave Blood Flow Meter." The disclosed apparatus includes orthogonal phase detection circuitry for providing Doppler information signals which have their phases shifted by 90° from each other.

Despite the variety of systems that have been devised and which rely on non-invasive techniques, drawbacks to the use of such systems in a clinical environment still exist. In that regard, a volume blood flow measuring system that incorporates the features of providing highly accurate volume fluid flow-related measurements, while being relatively inexpensive and easy to use would be very beneficial to medical diagnosticians and others interested in obtaining information relating to volume fluid flow.

Summary of the Invention

In accordance with the present invention, a clinically effective apparatus is provided for monitoring and measuring volume blood flow through a vessel or lumen located in the body of a patient. The apparatus includes a probe assembly for transmitting and receiving ultrasonic energy. The probe assembly includes a two-element transducer in which an outer transducer element is concentrically located relative to an inner transducer element. The transmission and reception by the transducer of ultrasonic energy is controlled using a processing/controlling unit that operatively communicates with the transducer using clock signals, amplifiers, and desired logic gates. In one embodiment, and unlike known prior art, the two-element transducer is uniquely configured to produce a 3 cm wide beam at 6 cm from the outer face of the probe assembly when the transducer elements are energized using a 2 MHz signal. In this configuration, the transducer includes an inner element and an outer element. The inner transducer element is a 2 mm disk and the outer transducer element is an annulus having a width of about 2 mm and being located about the outer periphery of the inner disk. This particular transducer is used in measuring volume blood flow through the ascending aorta. To transmit ultrasonic energy, a wide beam is generated by simultaneously energizing the outer and inner elements of the transducer. The transmitted energy is directed to the lumen of interest and the lumen reflects ultrasonic energy whereby returned energy is received by the transducer. The returned energy is defined in the form of a wide beam of energy and a narrow beam of energy using electrical signals generated by the transducer. The wide beam includes energy received by the inner transducer element and energy received by the outer transducer element. Similarly, the narrow beam includes energy received by the inner element and energy received by the outer element of the transducer. Both beams are received at the same time and simultaneously applied to demodulating circuitry. In contrast to known prior art, both the returned wide beam and narrow beam signals are demodulated or processed at the same time so that there is no delay between processing Doppler information from the wide beam and processing of Doppler information from the narrow beam.

In one embodiment, the demodulating circuitry includes eight channels, with each of the circuit channels including a multiplier circuit. Returned ultrasonic energy, including Doppler signal information, received by the inner transducer element is inputted to four of the multiplier circuits, while returned ultrasonic energy, including Doppler signal information, received by the outer transducer element is inputted to the other four multiplier circuits. Each of the multiplier circuits also receives a clock signal of a predetermined frequency and phase. For each multiplier circuit, each clock signal is multiplied or mixed with the inputted signal representative of received ultrasonic energy to output sums and differences of the two inputted signals. Four of the clock signals are provided to multiplier circuits in order to generate phase quadrature signals. The quadrature signals are phase shifted 90° relative to the normal or direct signals. The quadrature signals are used in determining the direction of the blood flow, i.e., whether the flow is towards or away from the probe assembly.

There is further processing of the received ultrasonic energy including the Doppler signal information whereby the two signal components representative of the wide beam are added or combined while the two signal components representative of the narrow beam are combined. The two wide beam quadrature signals and, similarly, the two narrow beam quadrature signals are also combined. The combined signals are applied to depth selection circuits and filter circuits to output Doppler signals or Doppler power spectrums representative of the difference between the frequency of transmitted energy and received energy. In the preferred embodiment, the normal and quadrature signals representative of the wide beam Doppler signals are sent to an AGC circuit. The AGC circuit reduces the amplitude fluctuations present in the Doppler signals. The widely varying signal amplitudes are caused by the scattering effect of the ultrasonic energy, which is due to the random collection of red blood cells being insonified. Because it is necessary to determine the ratio of the Doppler power in the wide beam to the Doppler power in the narrow beam, the effect of the use of the AGC circuit in the wide beam channel must be compensated for in the narrow beam channel. This is accomplished by using a feedback control signal to modify the power in the narrow beam that is the same as that being used to maintain a consistent signal amplitude for the wide beam. After the amplitudes of the Doppler signals have been adjusted, the power in the wide beam and the power in the narrow beam are determined. Each of the determined power outputs are then inputted to the processing/controlling unit for use in determining the ratio of the two power values. The ratio of the power from the wide beam to the power in the narrow beam is indicative of the cross-sectional area of the insonified lumen. In addition to determining the power output of the Doppler signals of the wide and narrow beams, the flow velocity of the blood is determined by means of a mean frequency estimator circuit which receives, as its inputs, the normal and phase quadrature signals of the Doppler power spectrum for the wide beam. The mean frequency that is determined by this circuit is directly proportional to the velocity of the blood at the insonified lumen area. The determined flow velocity is applied to a recording device which displays a signal representative of the flow velocity of the blood. In contrast to known systems, the trace or graph of the flow velocity is used in positioning the probe assembly on the patient's body to accurately measure blood volume flow. That is, the operator or user observes the trace of the flow velocity and, when a known or predetermined flow velocity trace is observed, the operator knows that the probe assembly is correctly positioned. Once the proper position of the probe assembly is achieved, the processing/controlling unit can then calculate volume blood flow with a high degree of accuracy by multiplying the current flow velocity by the ratio of the determined power Doppler outputs for the wide and narrow beams.

In view of this summary, a number of salient features of the present invention are easily recognized. The disclosed apparatus provides a workable implementation of generally theoretical studies and efforts in the area of measuring volume fluid flow. The apparatus of the present invention can be used in a clinical environment and incorporates techniques and features that achieve this principal objective. Circuitry is provided for simultaneously computing Doppler power from a wide beam and a narrow beam so that there is certainty that the power in the wide beam and the power in the narrow beam are determined during the time that the transducer is insonifying the exact same lumen area. Consequently, inadvertent movement of the probe assembly by the operator does not result in a determination of wide beam power for a different lumen area than the area for which the narrow beam power was found. The apparatus includes circuitry for generating phase quadrature signals in order to determine the direction of flow of the blood in the vessel of interest. Additionally, circuitry is provided to reduce amplitude fluctuations caused by the returned Doppler signals without adversely affecting the determination of the ratio of the power in the wide beam to the power in the narrow beam. A recording device is also provided so that the operator can observe the flow velocity trace in order to ensure that the probe assembly is correctly placed for accurately determining volume blood flow. Lastly, in one embodiment for monitoring and measuring volume blood flow in the ascending aorta, a uniquely configured probe assembly is utilized wherein the wide beam is produced having a desired width at a selected depth.

Additional advantages of the present invention will become readily apparent from the following discussion, when taken in conjunction with the accompanying drawings.

Brief Description of the Drawings

Fig. 1 is a block diagram of the present invention;

Fig. 2 is a further block diagram of the present invention diagramatically illustrating additional detail of the hardware of the present invention; and

Fig. 3 illustrates a graphic representation or data printout relating to blood flow from a typical adult including a flow velocity trace and traces of wide beam and narrow beam power.

Detailed Description of the Preferred Embodiments

With reference to Figs. 1 and 2, an apparatus embodying features of the present invention is diagrammatically illustrated. In conjunction with the principles on which the present invention is based, the subject matter found in U.S. Patent No. 4,067,236 to Hottinger is incorporated herein by reference.

The apparatus includes a probe assembly 10 including a transducer 12 for use in transmitting and receiving ultrasonic energy. In the embodiment illustrated, the transducer 12 includes an inner element 14 and an outer element 16 for use in transmitting to and receiving energy from a lumen area 18. In one preferred embodiment, the inner element 14 is a disk having a diameter of about 2 mm and the outer element 16 is a ring or annulus having a width of about 2 mm and being located about the outer periphery of the disk-shaped inner element 14. In this configuration, there is a very small gap between the inner and outer elements 14, 16 so that the two elements are able to operate independently. With this transducer construction, when a 2 MHz signal is applied to the inner and outer transducer elements, a uniform beam of about 3 cm in width is generated about 6 cm from the face of the transducer 12. This configured transducer 12 has particular utility in measuring volume blood flow in the ascending aorta when it is insonated from the suprasternal notch. Other particularly configured transducers can be provided for use in the present invention and the construction of the transducer depends upon the part of the body to be insonified.

The apparatus also includes a clock signal assembly 20, which communicates with the probe assembly 10. The clock signal assembly 20 is used to provide a number of clock or oscillating signals at a predetermined frequency and in which at least certain of the clock signals have a desired phase relationship relative to each other. The clock signal assembly 20 is controlled by a processing/controlling unit 22. The processing/controlling unit 22 is programmable and includes the necessary hardware and software for controlling the operation of the clock signal assembly 20, as well as other parts of the apparatus in determining volume blood flow.

With particular reference to Fig. 2, the clock signal assembly 20 includes a 2 MHz master oscillator 24, the output of which is applied to a number of clock selectors (CS) 26, 28. In a preferred embodiment, the 2 MHz master clock oscillator is derived from a 16 MHz master oscillator, i.e., the 16 MHz signal is divided down by appropriate logic to provide a desired number of clock signals having different phases thereby resulting in the generation of accurate phase quadrature signals. Each of the clock selectors 26, 28 is controlled by a data input from the processing/controlling unit 22. In connection with energizing the inner element 14 of the transducer 12, clock selector 26 is provided and, with respect to the outer transducer element 16, clock selector 28 is provided. The output of each clock selector 26, 28 communicates with an And gate 30, 32, respectively. The output of the And gate 30 is received by amplifier 34 while the output of the And gate 32 is inputted to amplier 36. The gain of each of the two amplifiers is controlled by a digital-analog converter (DAC) 38 or 40, with the output of the DAC 38 controlling the gain of the amplifier 34 and the output of the DAC 40 controlling the gain of the amplifier 36. The overall gain of the apparatus is controlled by means of a DAC 42. As can be seen in Fig. 2, the output of the amplifier 34 communicates with and energizes the inner transducer element 14 and the output of the amplifier 36 communicates with and energizes the outer transducer element 16.

The clock signal assembly 20 further includes receiving amplifiers 46, 48. The amplifier 46 communicates with the inner transducer element 14 and amplifies the signal representing returned ultrasonic energy received by this transducer element from the insonified lumen area 18, while the amplifier 48 amplifies the signal representing returned ultrasonic energy received by the outer transducer element 16 from the insonified lumen area 18. The outputs of the amplifiers 46, 48 are applied to demodulating circuitry 50 and direction discriminating circuitry 52. The output signals from the amplifiers 46, 48 can be defined or characterized as wide beam signals or narrow beam signals. The wide beam signals represent a wide beam of ultrasonic energy returned from the insonified lumen area 18 and the narrow beam signals represent narrow beam of ultrasonic energy returned from the insonified lumen area 18.

The clock assembly 20 further includes eight clock selectors 56a-56d and 58a-58d. The clock selectors 56 are associated with wide beam signals and the clock selectors 58 are associated with narrow beam signals, as will be subsequently explained. Each of the outputs of the clock selectors 56, 58 is a clock or oscillating signal and, in the embodiment shown, the clock selectors 56, 58 communicate with the master oscillator 24 to output a 2 MHz signal, with at least some of the outputted clock signals having a phase different from other of the clock signals. The clock signal outputs are also applied to the demodulating circuitry 50 and the direction discriminating circuitry 52.

The demodulating circuitry 50 is used to obtain Doppler signal information from the inputted signals representing the returned ultrasonic energy. The direction discriminating circuitry 52 also receives wide beam and narrow beam signals and is used in determining the direction of blood flow through the lumen area 18 with reference to the probe assembly 10. In particular, it is worthwhile to know whether the blood flow is towards the probe assembly 10 or away from the probe assembly 10. Such a determination enables the operator, for example, to know whether the blood vessel of interest is an artery or a vein. It should be noted that, although the direction discriminating circuitry 52 is identified separately from the demodulating circuitry 50, phase quadrature signals are also involved in the demodulating steps and the demodulating circuitry 50 essentially includes the direction discriminating circuitry 52.

As illustrated in Fig. 2, the demodulating circuitry 50 and the direction discriminating circuitry 52 include a number of multiplier circuits 60, 62, with the multiplier circuits 60a-60d being associated with or responsive to wide beam signals and the multiplier circuits 62a-62d being associated with or responsive to signals representative of the narrow beam. Also inputted to each of the multiplier circuits 60, 62 is a clock signal. The mixing of the returned beam signals and the clock signals results in signals being outputted from the multiplier circuits 60, 62 which are the sums and differences of the frequencies of the signals inputted thereto. As can be seen in Fig. 2, eight circuit channels are provided with four of the circuit channels being associated with the wide beam and four channels being associated with the narrow beam. Two of the wide beam associated channels develop normal signals representative of the wide beam while two of these channels develop quadrature signals, which are 90° out of phase relative to their respective normal signals. That is, the quadrature wide beam signal outputted by the multiplier circuit 60b has the same signal information as that outputted by the multiplier circuit 60a but is 90° out of phase. Similarly, there are four multiplier circuits 62 associated with the narrow beam with two normal signals being outputted by the multiplier circuits 62a, 62c, while quadrature signals are found at the outputs of the multiplier circuits 62b, 62d. Like the wide beam signals, the quadrature signal outputted by the multiplier circuit 62b includes the sums and differences of the frequencies of the signals applied thereto and is 90° out of phase relative to the output of the multiplier circuit 62a.

Each of the normal and quadrature signals representative of the received wide beam and the received narrow beam is applied to an amplifier 66, 68. In particular, the amplifiers 66a-66d receive either normal or quadrature signals representative of the wide beam while the amplifiers 68a-68d receive normal or quadrature signals representative of the narrow beam. The gain of each of the amplifiers 66, 68 can be controlled using one of the data latches (DL) 70. The output of each DL 70 is controlled using the processing/controlling unit 22. The amplified normal and quadrature signals are applied to adder circuits 72, 74. The normal signal outputted by the amplifier 66a and representative of the wide beam signal received by the inner transducer element 14 is combined in the adder circuit 72a with the amplified signal from the amplifier 66c, which is representative of the wide beam received by the outer transducer element 16. The adder circuit 72b combines the quadrature signals of these two wide beam related signals. Similarly, the adder circuit 74a receives as its inputs the normal signal from the amplifier 68a, which is representative of the narrow beam received by the inner transducer element 14 for combining it with the amplified signal from the amplifier 68c, which is representative of the narrow beam portion received by the outer transducer element 16. The adder circuit 74b receives the quadrature signals associated with the narrow beam. At the outputs of the adder circuits 72, 74, normal and quadrature signals remain that are separately representative of the wide beam and the narrow beam and include Doppler signal information, which is to be further processed.

In that regard, the demodulating circuitry 50 includes sample-and-hold circuits 76, 78. The sample-and-hold circuit 76a receives the normal wide beam signal outputted by the adder circuit 70a; the sample-and-hold circuit 76b receives the quadrature wide beam signal from the adder circuit 70b; the sample-and-hold circuit 78a receives the normal narrow beam signal from the adder circuit 72a; and the sample-and-hold circuit 78b receives the quadrature narrow beam signal from the adder circuit 72b. Each of the outputs of the sample-and-hold circuits 76, 78 is controlled using the processor/controlling unit 22. Each sample-and-hold circuit 76, 78 is adjusted or controlled in order to output narrow and wide beam signal information that represents a desired, predetermined depth associated with the returned ultrasonic energy, as is well known in the art. The outputs of the sample-and-hold circuits 76, 78 are applied to four band pass filters (BPF) 82, 84. The normal and quadrature signals associated with the wide beam are sent to the band pass filters 82a, 82b while the normal and quadrature narrow beam signals are transmitted to the band pass filters 84a, 84b. Each of the band pass filters filters the signals inputted thereto and outputs Doppler signal information or a Doppler power spectrum.

The normal and quadrature Doppler signals are then applied to flow separator circuits 86, 88, which are used in determining the direction of flow of the blood or fluid being insonified. As depicted in Fig. 2, the flow separator circuit 86 receives normal and quadrature Doppler signals associated with the wide beam and outputs a signal indicative of whether the flow is in a forward direction (Fw) in which the blood or fluid is moving towards the probe assembly 10 or a reverse direction (Rw) in which the blood or fluid is moving in a direction away from the probe assembly 10. Similarly, the flow separator circuit 88 receives the normal and quadrature Doppler signals associated with the narrow beam and outputs signals Fn and Rn indicative of whether the flow is in a forward or reverse direction, respectively.

In addition to being applied to the flow separator circuit 86, the normal and quadrature signals associated with the wide beam are applied to a switch 90, which communicates with an AGC circuit 94. Because the normal and quadrature Doppler signals widely fluctuate in amplitude, it has been found necessary to utilize the AGC circuit 94 in order to reduce the fluctuations and to provide a more constant or consistent output, as will be explained in greater detail in connection with a discussion of the operation of the apparatus.

To determine the necessary information for calculating the volume blood flow, the Doppler power spectrum or Doppler signal information associated with the wide beam is outputted from the AGC circuit 94 to a power measuring device 96 and also to a mean frequency estimator circuit 100. The power measuring device 96 is a well-known circuit and outputs a signal representative of the power in the wide beam, as discussed in the '236 patent to Hottinger. The mean frequency estimator circuit 100 is a conventional inplementation of a circuit for determining the mean frequency (Fd) of the Doppler power spectrum inputted thereto, in accordance with the principles disclosed in the Hottinger patent. The mean frequency is directly related to the velocity of the blood flowing through the insonified lumen area 18.

Referring back to the narrow beam channels or section of the apparatus, the normal and quadrature Doppler signals associated with the narrow beam are applied to a switch 102. Also inputted to the switch 102 are narrow beam signals indicative of whether the flow is in a forward (Fw) or reverse direction (Rw). The output of the switch 102 is sent to the power measuring device 104 for the narrow beam. The power measuring device 104 is comparable to the power measuring device 96 and outputs a signal representative of the power in the Doppler power spectrum associated with the narrow beam. Also operatively associated with the power measuring device 104 is a feedback control signal generated by the AGC circuit 94. This control signal is used to avoid inaccuracies in determining the ratio of Pw to Pn, as will be subsequently explained in greater detail. Each of the determined outputs Fd, Pw, and Pn are inputted to the processing/controlling unit 22 for use in determining the volume blood flow of the insonified lumen area 18. In connection with receiving the mean frequency Fd, the processing/controlling unit 22 utilizes the determined magnitude of Fd to calculate flow velocity of the blood or fluid and output the same to a recording device 106. Consequently, the operator is able to view a flow velocity trace or graph during the time that the probe assembly 10 is positioned at or near a desired part of the body of a patient that receives ultrasonic energy.

As also seen in the wide beam circuit channel of Fig. 2, a switch 108 receives the output from the flow separator circuit 86. The output of the switch 108 is sent to a phase processor 110 for producing a quadrature signal for the signal representing forward flow Fw or the signal representing reverse flow Rw, whichever is applicable. The phase processor 110 outputs normal and quadrature signals associated with the signal then being outputted by the flow separator circuit 86. The normal and quadrature signals from the phase processor

110 are applied to the switch 90, which can be controlled by the operator of the apparatus so that, instead of normal and quadrature signals from the band pass filters 82a, 82b being applied to the AGC circuit 94, the normal and quadrature signals from the phase processor 110 are sent.

With further reference to Fig. 2, the apparatus includes circuitry for use in permitting the operator to listen to the returned Doppler signal information. In particular, left and right signal outputs are generated for input to a loud speaker or earphones so that the operator is able, under switch control, to listen to selected signals representative of the Doppler information found in the returned wide and narrow beams of ultrasonic energy, including both normal and quadrature signals, as well as the flow separated signals outputted from the flow separator circuits 86, 88. The amplifier 112 outputs the left output signal and the amplifier 114 outputs the right output signal. A pair of amplifiers 116, 118 amplify the input signal applied thereto from operator-controlled switches 120, 122, respectively. The gain of each of the amplifiers 116, 118 is controlled using the processing/controlling unit 22 and a DAC 124.

Lastly, in the preferred embodiment, the apparatus includes a calibration oscillator 126, which is capable of outputting one of a number of signals having a predetermined frequency. Preferably, the outputted signal is in the range of 2-6 KHz. The calibration oscillator 126 is used in calibrating and checking the accuracy of the power measuring device 96, mean frequency estimator circuit 100, and power measuring device 104, as well as hardware and software of the processing/controlling unit 22.

With respect to the operation of the apparatus, the probe assembly 10 is placed on or near the patient's skin at a position to suitably insonify a desired lumen area 18. The operator of the apparatus also locates the recording device 106 in a position that permits easy observation of the flow velocity trace. Upon activation by the operator and under the control of the processing/controlling unit 22, clock signals are transmitted, via the And gates 30, 32 to the amplifiers 34, 36. A transmitted wide beam of energy is generated by applying amplified clock signals to the inner and outer transducer elements 14, 16. In the preferred embodiment, the wide beam is produced by clock signals simultaneously applied to the inner and outer transducer elements 14, 16, with the signal applied to the outer transducer element 16 being 180° out of phase relative to the signal applied to the inner transducer element 14. The transmitted wide beam of energy is received by the lumen area 18 of interest and some of the ultrasonic energy contacted by the lumen area and the red corpuscles of blood is reflected back to the probe assembly 10. The returned ultrasonic energy is simultaneously received by both the inner and outer transducer elements 14, 16. During the time associated with the reception of reflected ultrasonic energy, the processing/controlling unit 22 prevents the transmission of ultrasonic energy to the lumen area 18. Consequently, there is a predetermined time for transmitting ultrasonic energy and a different predetermined time for receiving reflected ultrasonic energy so that no overlap is created.

With regard to the returned ultrasonic energy, wide and narrow beam signals, comprising the sums and differences of the signal frequencies, are produced using the clock selectors 56, 58 and the multiplying circuits 60, 62. A signal representative of the wide beam includes outputs from the inner and outer transducer elements 14, 16, with the outputs being 180° out of phase. The electrical representation of the returned narrow beam also includes signals outputted by both the inner and outer transducer elements 14, 16, but with these signals being substantially in phase. At the same time, both signals representative of the wide beam and the narrow beam, including generated quadrature signals, are demodulated by the demodulating circuitry 50 with the quadrature signal generating circuitry forming part of the direction discriminating circuitry 52 for use in determining the direction of blood flow in the insonified lumen area 18.

As the signals, including Doppler information, pass through the demodulating circuitry 50, the two sets of signals, normal and quadrature signals generated using the outputs from the two transducer elements 14, 16, representative of the wide beam are combined and the two sets of signals representative of the narrow beam are also combined. Under control of the processing/controlling unit 22, the sample-and-hold circuits 76, 78 output wide and narrow beam signals providing information for the desired depth associated with the lumen area 18 being insonified. The band pass filters 82, 84 of the wide and narrow beam channel circuits, each having a band pass controllable by the processing/controlling unit 22, pass signals having a frequency corresponding to the frequency difference between the transmitted ultrasonic energy and the received ultrasonic energy so that normal and quadrature Doppler signals or Doppler power spectrums are outputted by the filters 82, 84.

The normal and quadrature Doppler signals representative of the wide beam are sent to the AGC circuit 94 where unwanted amplitude fluctuations are removed. Because the ratio of Pw to Pn is found in determining volume blood flow, it is necessary that no inaccuracy occur in this result due to the adjustment by the AGC circuit 94 of the normal and quadrature Doppler power spectrums associated with the wide beam. This is accomplished by using the same control signal, developed by the AGC circuit 94 for controlling the amplitude fluctuations in the wide beam Doppler signals, to control the amplitudes of the narrow beam Doppler signals.

Since the ratio of the two powers is obtained, modifying Doppler signals associated with the wide beam and also those associated with the narrow beam, avoids the introduction of an inaccuracy because of the use of the AGC circuit 94. For example, if the Doppler power associated with the wide beam increases, then the AGC circuit 94 compensates by decreasing its control voltage, which in turn, reduces the level of the Doppler power associated with the narrow beam. This has an overall effect of keeping the power signal associated with the wide beam at a constant level but varies the power level in the narrow beam. In the case in which the Doppler power in the wide beam increases, which occurs when there is a large flow lumen area 18, then the Doppler power in the wide beam will remain substantially constant but the control voltage from the AGC circuit 94 will reduce the Doppler power associated with the narrow beam. The overall effect is the same since the ratio of Pw to Pn is taken and, although the Doppler power associated with the wide beam has been held substantially constant, the ratio of the power in the wide beam to the power in the narrow beam increases because the Doppler power associated with the narrow beam has been reduced. For each of the power measuring devices 96, 104, the Doppler power spectrum associated with each of the respective narrow and wide beams is processed to determine Pw and Pn. The Doppler power spectrum associated with the wide beam after being adjusted in amplitude, is also used to determine the mean frequency (Fd) thereof by means of the mean frequency estimator circuit 100. The processing/controlling unit 22 receives the mean frequency and determines the flow velocity of the blood through the insonified lumen area 18. Signals representative of the flow velocity at each instance in time are applied to the recording device 106 so that the operator is able to view a trace of the blood flow velocity. With reference to Fig. 3, the top graph is a representative flow velocity trace of blood flow from the heart of a typical adult. In addition to flow velocity, the magnitudes of the determined powers Pw and Pn are inputted to the processing/controlling unit 22, which develops signals for input to the recording device 106 whereby wide beam power and narrow beam power traces are also provided. In the preferred embodiment, the operator also selects one of the available inputs to the left and right signal outputs and listens to the Doppler signals using the loud speaker or earphones.

Before relying on a calculation of the volume blood flow by the processing/controlling unit 22, the operator checks the flow velocity and power traces on the recording device 106, as well as the sounds associated with the Doppler information found in the left and right output signals. In the case of the flow velocity trace, the operator determines whether the amplitudes of the periodic signals are substantially at a maximum and have a substantially consistent amplitude. When this occurs, the operator knows that the probe assembly 10 and the transducer 12 are properly located for insonifying the desired lumen area 18. If the flow velocity trace did not provide such an indication, the position of the probe assembly 10 is changed until the known flow velocity trace is realized.

Upon achieving desired positioning of the probe assembly 10 and an expected flow velocity trace, an accurate determination of volume blood flow can be made since the values of the mean frequency and the powers in the wide and narrow beams are at their most accurate levels for the desired, insonified lumen area 18. The calculation of volume blood flow associated with the lumen area 18 is made by the processing/controlling unit 22 and a visual representation of the determined magnitude can be provided on the recording device 106 in units of liters/minute.

It should be appreciated that a number of modifications can be made to the present invention without departing from the inventive subject matter. First, although quadrature signals are generated for both narrow and wide beam signals, it is only necessary to generate quadrature signals for one of the two beams in order to determine the direction of flow. Second, the AGC circuit could be responsive to Doppler signals associated with the narrow beam and a control signal developed to modify the Doppler signals associated with the wide beam. However, it has been found that greater sensitivity is achieved by positioning the AGC circuit in the wide beam circuit channel. Although the quadrature signal associated with the wide beam is illustrated in Fig. 2 as the input to the power measuring device for the wide beam, the normal signal outputted by the AGC circuit could be used in determining the power associated with the wide beam. Further changes could be made to the embodiment of Fig. 2 without affecting the operability of the novel aspects of the present invention.

Based on the detailed description, a number of meaningful advantages of the present invention are immediately discerned. An apparatus for measuring volume blood or fluid flow is provided which can be readily operated in a clinical environment. The particular implementation disclosed herein results in an accurate determination of volume blood flow because of the simultaneous processing of narrow beam and wide beam signal information and proper placement of the probe assembly due to the ability to observe a trace of blood flow velocity. In addition, unwanted amplitude fluctuations in the Doppler power spectrum are removed without jeopardizing the determination of the power associated with the wide and narrow beams. Further, a preferably constructed transducer is disclosed for generating a wide uniform beam of ultrasonic energy for monitoring and measuring volume blood flow through the ascending aorta. The apparatus also incorporates an effective way for determining the direction of fluid flow.

What Is Claimed Is:

1. A method for use in measuring volume fluid flow, comprising:

providing transducer means having a plurality of transducer elements;

locating said transducer means in a position for monitoring the flow of fluid through vessel means;

transmitting ultrasonic energy directed towards the vessel means using said transducer means;

receiving returned ultrasonic energy from said flowing fluid using said transducer means wherein a wide beam of returned ultrasonic energy and a narrow beam of ultrasonic energy are defined;

developing signals representative of said wide beam and said narrow beam;

processing said signals to provide a Doppler power spectrum associated with each of said wide beam and said narrow beam;

obtaining a control signal using said Doppler power spectrum associated with one of said wide beam and said narrow beam;

controlling signal amplitudes of said Doppler power spectrums of each of said wide beam and said narrow beam using said same control signal.

2. A method, as claimed in Claim 1, wherein:

said obtaining step includes obtaining a control signal using said Doppler power spectrum associated with said wide beam.

3. A method, as claimed in Claim 1, further including:

determining the power associated with each of said wide beam and said narrow beam and calculating the ratio of said wide beam power and said narrow beam power.

4. A method, as claimed in Claim 1, further including:

determining the mean frequency associated with said Doppler spectrum of one of said wide beam and said narrow beam and using said mean frequency to determine flow velocity of the fluid.

5. A method, as claimed in Claim 4, further including:

providing a visual representation of said flow velocity, observing said flow velocity, and making an accurate determination of volume fluid flow in the vessel means after a known, predetermined representation of said flow velocity is observed.

6. A method, as claimed in Claim 1, wherein:

said processing step includes processing signals representative of said wide beam at the same time signals are being processed representative of said narrow beam.

7. A method, as claimed in Claim 1, wherein:

said transducer means includes an outer element and an inner element and said wide beam is defined by a first signal component generated using said inner element and a second signal component using said outer element, said first and second signal components being out of phase.

8. A method, as claimed in Claim 7, wherein:

said narrow beam is defined by a first signal component generated using said inner element and a second signal component generated using said outer element, said first and second signal components being substantially in phase.

9. A method, as claimed in Claim 1, further including:

generating a plurality of quadrature signals using oscillator signals and returned ultrasonic energy.

10. A method, as claimed in Claim 9, wherein:

said plurality of quadrature signals includes two quadrature signals associated with said wide beam and two quadrature signals associated with said narrow beam.

11. A method for use in measuring volume fluid flow, comprising:

providing transducer means having a first transducer element and a second transducer element;

locating said transducer means in a position for monitoring the flow of fluid through vessel means;

transmitting ultrasonic energy directed towards the flowing fluid using said first and second transducer elements;

receiving returned ultrasonic energy from the flowing fluid using said first transducer element and said second transducer element to define a wide beam of returned ultrasonic energy and a narrow beam of returned ultrasonic energy;

developing normal and quadrature signals associated with at least one of said wide beam and said narrow beam using returned ultrasonic energy received by said first transducer element, each of said normal and quadrature signals associated with said first transducer element including Doppler signal information;

developing normal and quadrature signals associated with at least one of said wide beam and said narrow beam using returned ultrasonic energy received by said second transducer element, each of said normal and quadrature signals associated with said second transducer element including Doppler signal information;

processing one or more of said normal and quadrature signals to determine a mean frequency associated with said Doppler signal information and to determine power in said wide beam and power in said narrow beam; and

determining the direction of flow of the fluid using one or more of said quadrature signals.

12. A method, as claimed in Claim 11, wherein said developing steps include:

generating normal and quadrature signals associated with said wide beam using returned ultrasonic energy received by said first transducer element;

generating normal and quadrature signals associated with said wide beam using returned ultrasonic energy received by said second transducer element;

generating normal and quadrature signals associated with said narrow beam using returned ultrasonic energy received by said first transducer element; and

generating normal and quadrature signals associated with said narrow beam using returned ultrasonic energy received by said second transducer element.

13. A method, as claimed in Claim 12, wherein said developing steps include:

mixing a first clock signal with said normal signal outputted by said first transducer element and associated with said wide beam; and

simultaneously mixing a second clock signal with said normal signal outputted by said second transducer element and associated with said wide beam, said first clock signal and said second clock signal being out of phase.

14. A method, as claimed in Claim 13, wherein:

said second clock signal is 180° out of phase from said first clock signal.

15. A method, as claimed in Claim 13, wherein said developing steps include:

mixing a third clock signal with said normal signal outputted by said first transducer element and associated with said narrow beam; and

simultaneously mixing a fourth clock signal with said normal signal outputted by said second transducer element and associated with said narrow beam, said third clock signal being substantially in phase with said fourth clock signal.

16. A method for use in measuring volume fluid flow, comprising:

providing transducer means having a first transducer element and a second transducer element;

locating said transducer means in a position for monitoring the flow of fluid through a vessel means;

transmitting ultrasonic energy directed towards the flowing fluid using said transducer means;

receiving returned ultrasonic energy from the flowing fluid using said transducer means to define a wide beam of returned ultrasonic energy and a narrow beam of returned ultrasonic energy;

providing four circuit channels, two of said circuit channels being responsive to inputs from said first transducer element and two of said circuit channels being responsive to inputs from said second transducer element;

developing Doppler signals representative of power in said wide beam using said first and third circuit channels;

developing Doppler signals, simultaneously with the development of Doppler signals representative of power in the wide beam, representative of power in the narrow beam using said second and fourth circuit channels; and

determining power in said wide beam and determining power in said narrow beam at the same time.

17. A method for use in measuring volume fluid flow, comprising:

providing transducer means having an inner transducer element and an outer transducer element concentric with said inner transducer element;

locating said transducer means in a position for monitoring the flow of fluid through a vessel means;

transmitting ultrasonic energy directed towards the flowing fluid in the vessel means using said outer and inner transducer elements;

receiving returned ultrasonic energy from the flowing fluid using said outer element and said inner element to define a wide beam of returned ultrasonic energy and a narrow beam of returned ultrasonic energy;

generating normal and quadrature signals representative of said wide beam and said narrow beam using oscillating signals of a predetermined frequency and phase;

processing at least some of said signals to develop a Doppler power spectrum associated with each of said wide beam and said narrow beam;

determining a mean frequency associated with said Doppler power spectrum of one of said wide beam and said narrow beam;

determining flow velocity of the fluid using said mean frequency;

providing a visual representation of said flow velocity of the fluid;

observing said visual representation of said flow velocity of the fluid; and

outputting an accurate determination of volume fluid flow after observing that the visual representation of said flow velocity corresponds to a known, predetermined representation indicating that said transmitted ultrasonic energy is being received by the vessel means at a desired location.

18. A method for use in measuring volume fluid flow, comprising:

providing transducer means having a plurality of transducer elements;

locating said transducer means in a position for monitoring the flow of fluid through vessel means;

transmitting only a wide beam of ultrasonic energy directed towards the vessel means using said transducer means;

receiving returned ultrasonic energy from the flowing fluid;

defining a wide beam of energy using said received ultrasonic energy;

defining a narrow beam of energy using said received ultrasonic energy;

developing signals representative of said wide beam and said narrow beam;

processing said signals to provide a value of Doppler power associated with each of said wide beam and said narrow beam;

determining flow velocity of the fluid; and

determining volume fluid flow using said Doppler power values and said flow velocity.

19. A method, as claimed in Claim 18, wherein:

said providing of said transducer means includes providing a first transducer element and a second transducer element concentrically located relative to said first transducer element and said transmitting of said wide beam of ultrasonic energy includes energizing said first transducer element using a first signal and energizing said second transducer element using a second signal, said second signal being out of phase relative to said first signal.

20. A method, as claimed in Claim 18, wherein:

said providing of said transducer means includes providing a first transducer element and a second transducer element concentrically located relative to said first transducer element, said transmitting of said wide beam of ultrasonic energy includes energizing both said first and second transducer elements, said defining of said wide beam includes using both said first and second transducer elements, and said defining of said narrow beam includes using both said first and second transducer elements.

21. A method, as claimed in Claim 19, wherein:

said second signal is substantially 180° out of phase relative to said first signal.

22. An apparatus for use in measuring volume fluid flow, comprising:

transducer means having a first transducer element and a second transducer element, said transducer means for transmitting ultrasonic energy in a direction towards a vessel means containing moving fluid and for receiving returned ultrasonic energy from the moving fluid, said transducer means being used to define a wide beam of returned ultrasonic energy and a narrow beam of returned ultrasonic energy and for developing signals representative of said wide beam and said narrow beam;

means for processing said signals to output a Doppler power spectrum associated with each of said wide beam and said narrow beam;

means for determining the power in said wide beam and in said narrow beam using each of said Doppler power spectrums;

means for calculating the ratio of said wide beam power to said narrow beam power; and

means for controlling signal amplitudes of said Doppler power spectrum of one of said wide beam and said narrow beam without affecting said ratio of said wide beam power and said narrow beam power.

23. An apparatus, as claimed in Claim 18, wherein:

said means for controlling includes means for generating a control signal using said Doppler power spectrum of one of said wide beam and said narrow beam and wherein said control signal operatively communicates with said means for determining the power in the other one of said Doppler power spectrum for use in adjusting the value of the power thereof.

24. An apparatus, as claimed in Claim 19, wherein:

said control signal is obtained using said Doppler power spectrum of said wide beam.

25. An apparatus, as claimed in Claim 18, wherein:

said means for processing includes means for providing a 2 MHz signal and wherein said first element is an outer ring having a width of about 2 mm and said transmitted beam has a width of about 3 cm at a distance of about 6 cm from said transducer means.

26. An apparatus, as claimed in Claim 18, wherein said means for processing includes:

first circuit channel means associated with said wide beam; and

second circuit channel means associated with said narrow beam, said first and second circuit channel means processing Doppler signal information at the same time for use in determining the power in said wide beam at the same time said power in said narrow beam is determined.

27. An apparatus, as claimed in Claim 18, wherein:

said means for processing includes means for generating a plurality of quadrature signals, at least two of said quadrature signals being associated with one of said wide beam and said narrow beam.

28. An apparatus, as claimed in Claim 18, wherein said means for processing includes:

means for generating a first clock signal for combining with a signal outputted by said first transducer element and associated with said wide beam;

means for generating a second clock signal for combining with a signal outputted by said second transducer element and associated with said wide beam;

means for generating a third clock signal for combining with a signal outputted by said first transducer element and associated with said narrow beam; and

means for generating a fourth clock signal for combining with a signal outputted by said second transducer element and associated with said narrow beam, and wherein each of said first, second, third and fourth clock signals are being combined at substantially the same time with their respective signals from said transducer means.

29. An apparatus, as claimed in Claim 18, wherein:

said means for processing includes calculating means for determining volume fluid flow using said mean frequency and said power ratio.

30. An apparatus for use in measuring volume fluid flow, comprising:

transducer means including a plurality of transducer elements for transmitting and receiving ultrasonic energy, said received ultrasonic energy being in the form of a relatively wide beam of energy and a relatively narrow beam of energy;

direction discriminating means responsive to said transducer means and having a first quadrature signal associated with said wide beam and being generated using ultrasonic energy received by said first transducer element, a second quadrature signal associated with said wide beam and being generated using ultrasonic energy received by said second transducer element, a third quadrature signal associated with said narrow beam and being generated using ultrasonic energy received by said first transducer element, and a fourth quadrature signal associated with said narrow beam and being generated using ultrasonic energy received by said second transducer element; and

processing means for determining power in said wide beam and for determining power in said narrow beam, said processor means further including means for determining a mean frequency associated with one of said wide beam and said narrow beam; and

means for determining volume fluid flow using said mean frequency and said wide beam power and said narrow beam power.

31. A transducer for use in measuring volume blood flow through the ascending aorta, comprising;

an inner transducer element being in the shape of a disk having a diameter of about 2 mm; and

an outer transducer element positioned outwardly of said inner transducer element and being substantially concentric relative to said inner transducer element, said outer transducer element being in the shape of a ring having a width of about 2 mm and, when each of said inner and outer transducer elements is energized using about a 2 MHz signal, said transducer transmits a relatively uniform beam of ultrasonic energy having a width of about 3 cm at a distance of about 6 cm from said transducer.

32. A method for use in measuring volume blood flow through the ascending aorta, comprising:

providing a disk-shaped inner transducer element having a width of about 2 mm;

providing a ring-like outer transducer element having a width of about 2 mm;

energizing each of said inner and outer transducer elements using about a 2 MHz signal; and

transmitting to the ascending aorta a beam of ultrasonic energy having a width of about 3 cm at a distance of about 6 cm from said inner and outer transducer elements.

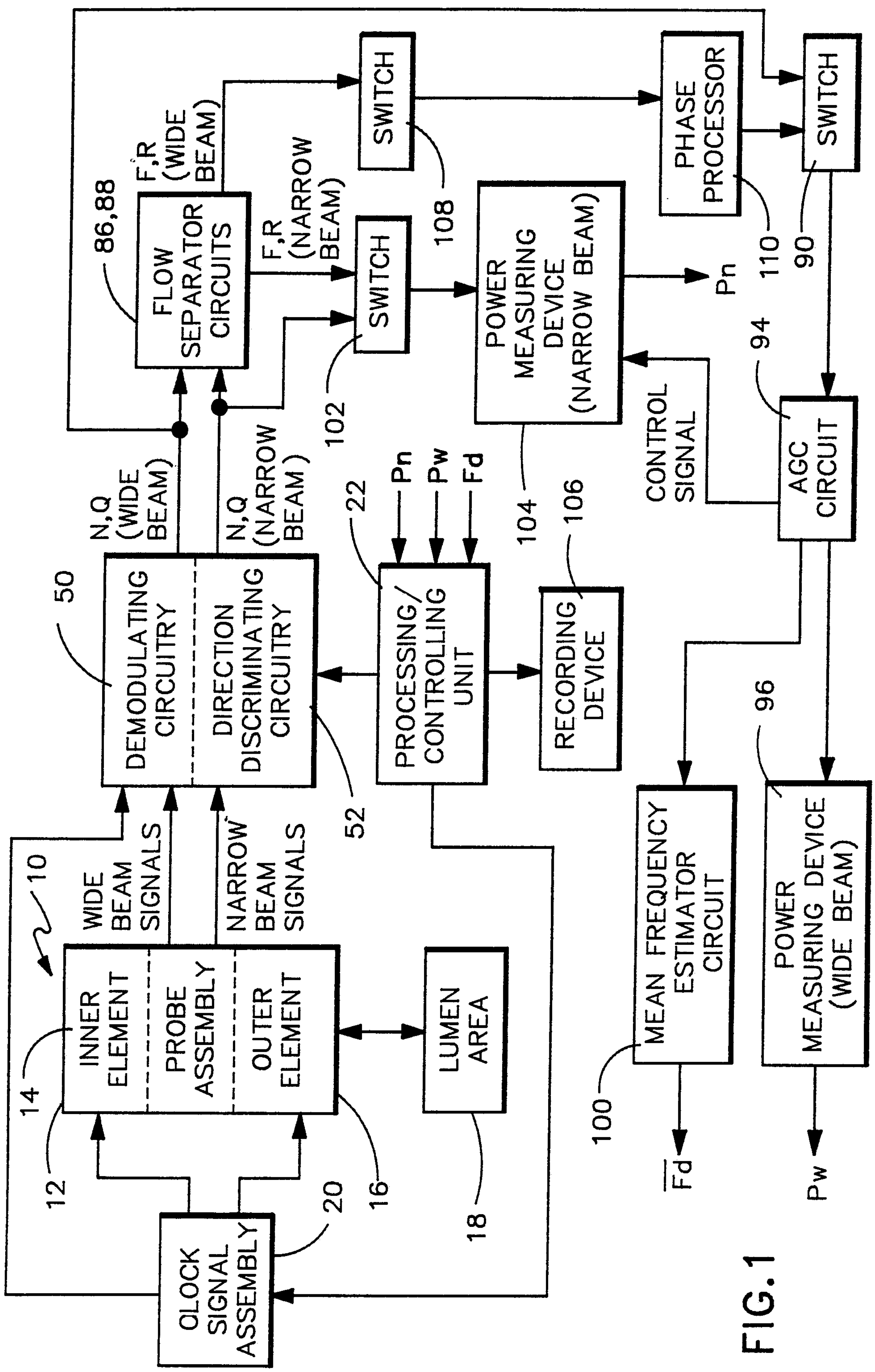
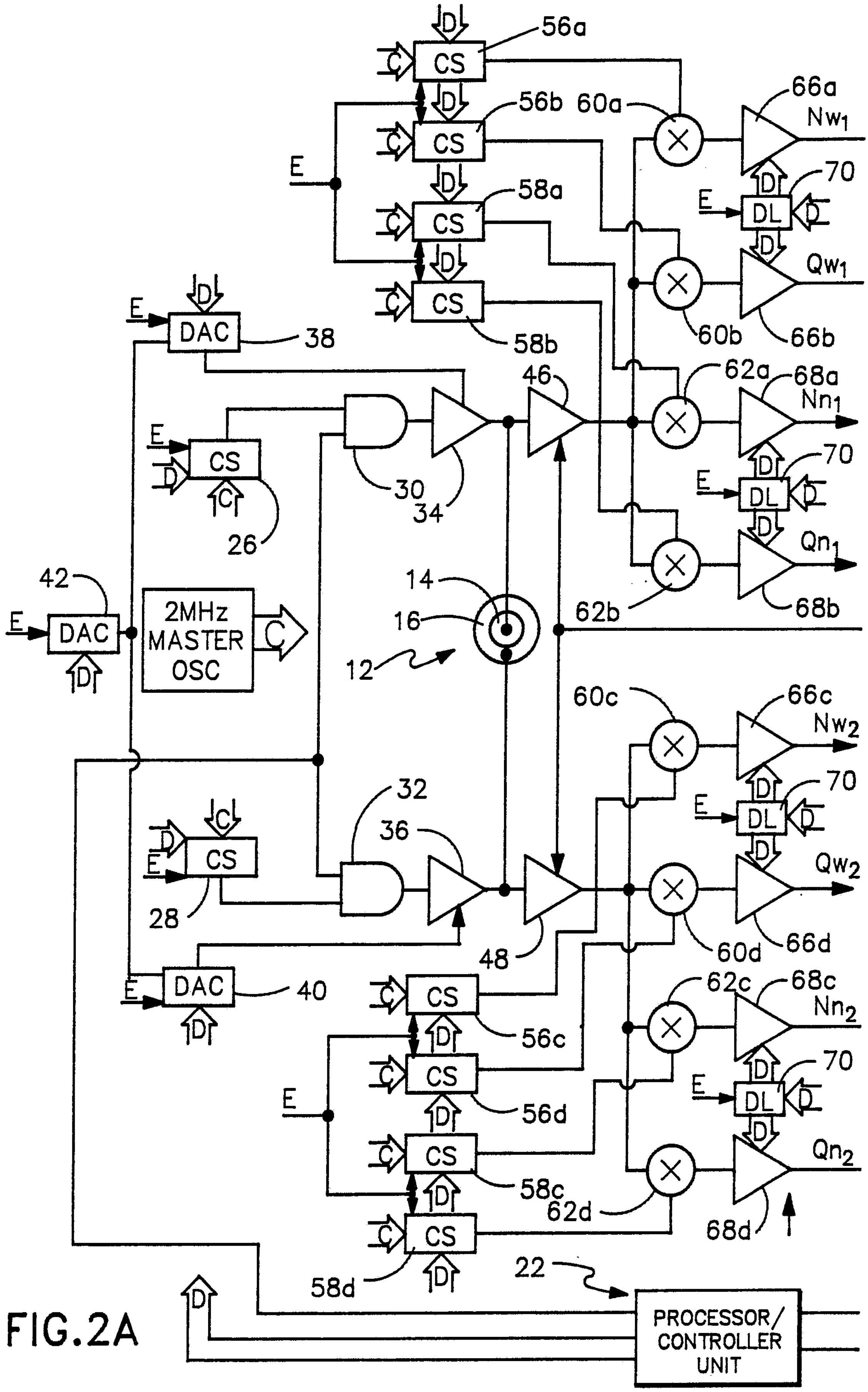

CLOCK SIGNAL ASSEMBLY
20
12
14
16
INNER ELEMENT
PROBE ASSEMBLY
OUTER ELEMENT
LUMEN AREA
18
10
WIDE BEAM SIGNALS
NARROW BEAM SIGNALS
DEMODULATING CIRCUITRY
DIRECTION DISCRIMINATING CIRCUITRY
50
52
N,Q (WIDE BEAM)
N,Q (NARROW BEAM)
PROCESSING/ CONTROLLING UNIT
22
Pn
Pw
Fd
RECORDING DEVICE
106
FLOW SEPARATOR CIRCUITS
86,88
F,R (WIDE BEAM)
F,R (NARROW BEAM)
SWITCH
102
SWITCH
108
POWER MEASURING DEVICE (NARROW BEAM)
104
Pn
PHASE PROCESSOR
110
SWITCH
90
CONTROL SIGNAL
AGC CIRCUIT
94
MEAN FREQUENCY ESTIMATOR CIRCUIT
100
Fd
POWER MEASURING DEVICE (WIDE BEAM)
96
Pw

FIG. 1



CS
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56b
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66a
Nw1
E
58a
70
DL
Qw1
DAC
38
58b
60b
66b
46
62a
68a
Nn1
30
34
26
Qn1
42
14
16
62b
68b
2MHz MASTER OSC
12
60c
66c
Nw2
32
36
Qw2
28
48
60d
66d
40
56c
62c
68c
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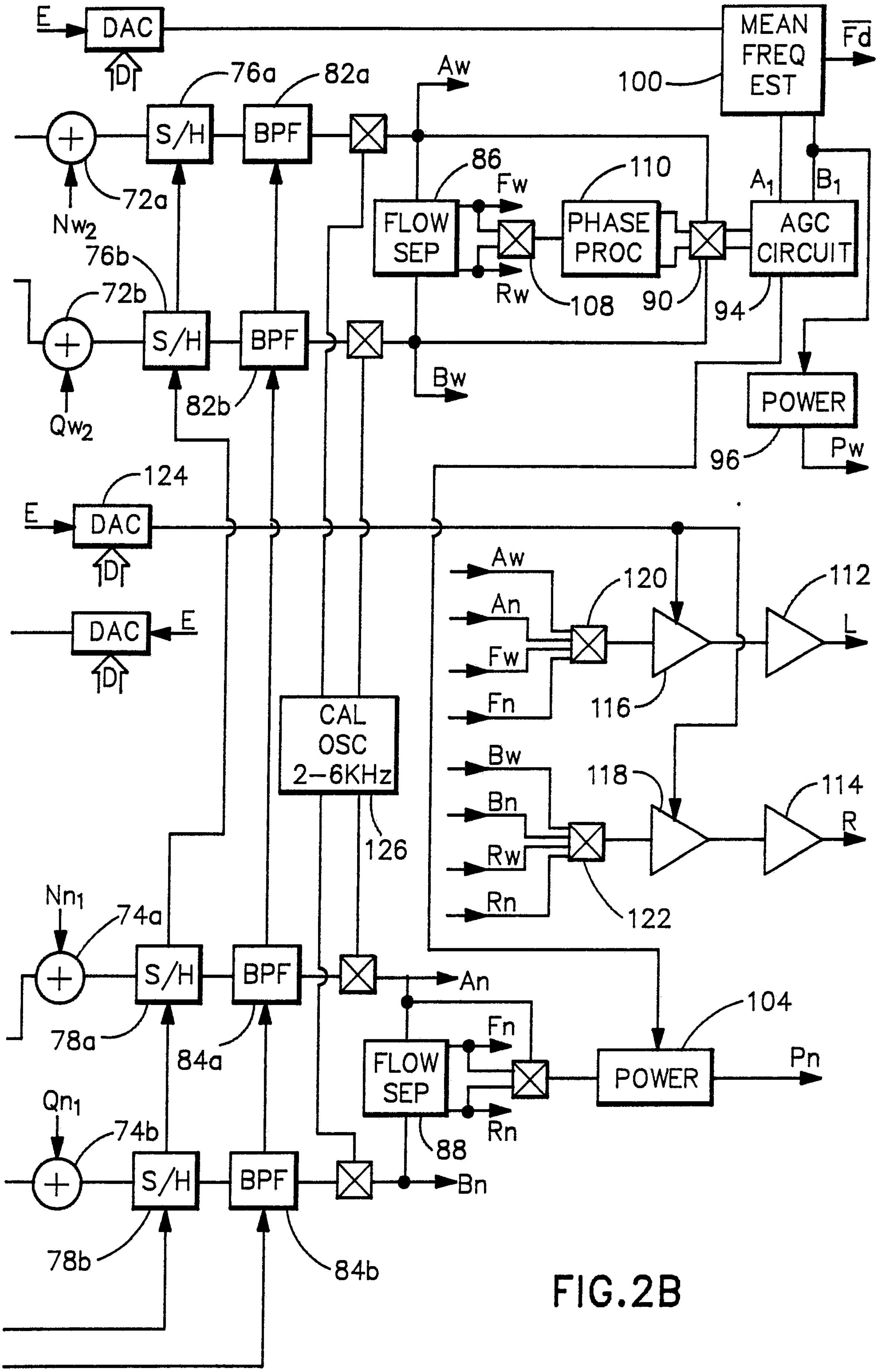
22
PROCESSOR/ CONTROLLER UNIT
C
D

FIG.2A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AGC CIRCUIT
76b
72b
Rw
108
90
94
Bw
82b
Qw2
POWER
96
Pw
124
DAC
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DAC
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An
Fw
Fn
120
116
112
L
Bw
Bn
Rw
Rn
118
122
114
R
CAL OSC 2-6KHz
126
Nn1
74a
78a
84a
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Fn
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Rn
88
POWER
104
Pn
Qn1
74b
78b
84b
Bn

FIG.2B

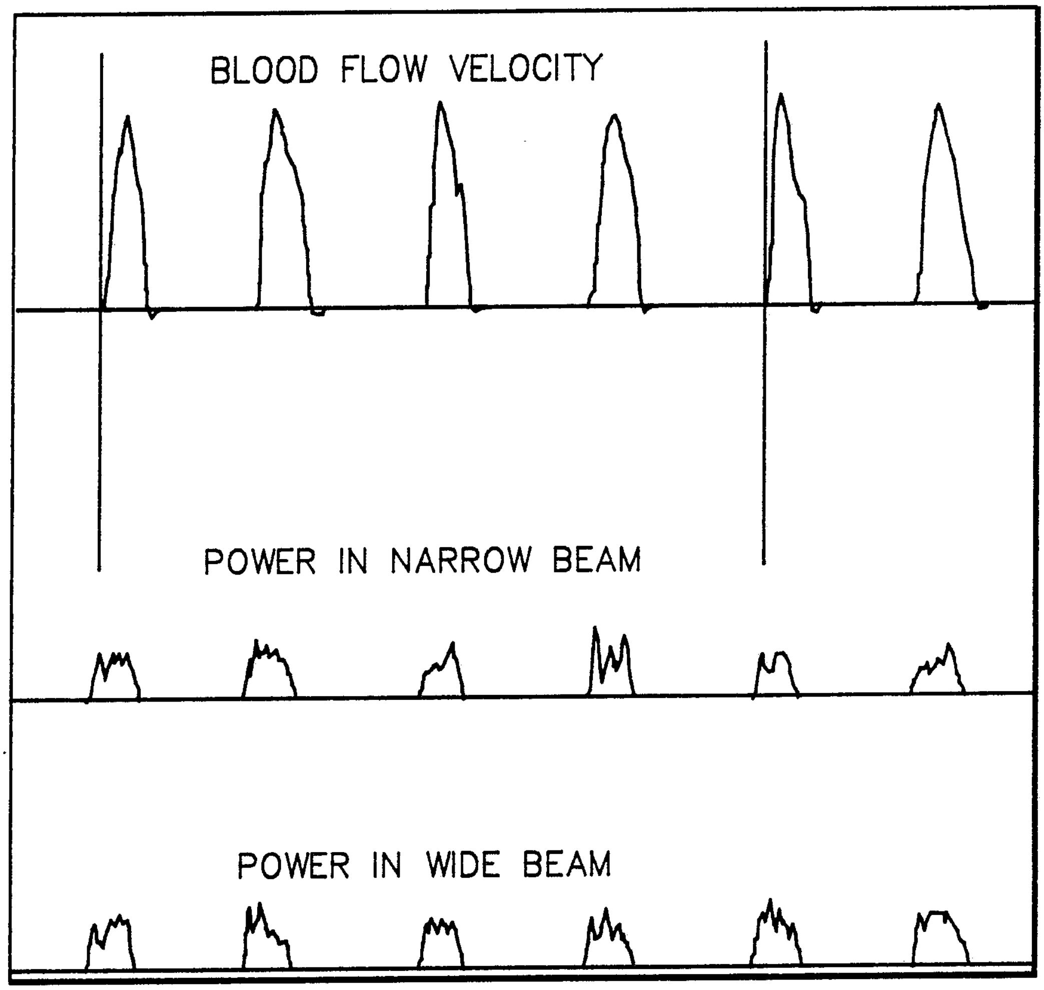

FIG.3

INTERNATIONAL SEARCH REPORT

International Application No PCT/US87/02179

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(4): A61B 10/00
U.S. Cl: 128/663, 73/861.25

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
U.S.	128/660,663 73/861.25 367/90

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [6]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
Y	US,A, 4,493,216 (HASSLER) 15 JANUARY 1985 See column 2 line 53 - column 3 line 10	1,3-6,9,22, 26,29
Y	US,A, 4,541,437 (AMEMIYA) 17 SEPTEMBER 1985 See column 2, line 56 - column 3 line 6	1,3-6,9,22, 26,29
Y	US,A, 4,060,763 (HASSLER) 29 NOVEMBER 1977 See column 1 lines 30-63	2,23,24
Y	US,A, 4,431,936 (FU ET AL) 14 FEBRUARY 1984 See column 6 lines 8-12	6-10,25-28, 30-32
Y	US,A, 4,155,259 (ENGELER) 22 MAY 1979 See column 1 lines 7-10, column 5 lines 25-47 and Figs. 4A, 4C	7-19,27,28, 30
Y	US,A, 4,534,357 (POWERS) 13 AUGUST 1985 See Abstract and column 1 line 26 - column 2 line 18	10,27,28,30,
Y	US,A, 4,257,278 (PAPADOFRANGAKIS ET AL) 24 MARCH 1981, See column 2 lines 25-45	11-19

* Special categories of cited documents: [15]
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
06 NOVEMBER 1987	09 DEC 1987.
International Searching Authority [1]	**Signature of Authorized Officer [20]**
ISA/US	Francis J. Jaworski

Form PCT/ISA/210 (second sheet) (May 1986)

International Application No. PCT/US87/02179

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

Y	US,A, 4,530,363 (BRISKEN) 23 JULY 1985 See column 2 lines 48-63	31-32
A	US,A, 4,155,260 (ENGELER ET AL) 22 MAY 1979 See column 2 lines 7-50	

V.☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [10]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1.☐ Claim numbers , because they relate to subject matter [12] not required to be searched by this Authority, namely:

2.☐ Claim numbers , because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [13], specifically:

VI.☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [11]

This International Searching Authority found multiple inventions in this international application as follows:

1.☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2.☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3.☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4.☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.