IMPLANTABLE ULTRASONIC BLOOD FLOWMETERS

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Summary Accurate measurement of pulsatile blood flow can be achieved on a chronic basis in research animals through the use of totally implantable ultrasonic flowmeters. The continuous wave Doppler flowmeter provides an attractive technique for measurement of flow velocity at a particular location such as the center of the lumen; the pulsed Doppler flowmeter is attractive for measurement of flow velocity distribution or profile across the vessel and lumen diameter, and hence volume flow. Both instruments can be electronically precalibrated and exhibit no baseline or scale factor changes during chronic experiments. Custom designed silicon monolithic integrated circuits offer significant advantages in reduced size and power drain as well as improved reliability in these instruments.

Introduction Accurate measurement of pulsatile blood flow is of major importance in cardiopulmonary research and development. It is particularly attractive to perform this measurement on a chronic basis in research animals under a variety of normal and abnormal conditions. The most promising instruments available for this purpose are ultrasonic flowmeters. This paper briefly reviews their principles of operation as well as their primary capabilities and limitations. In addition, a discussion is presented of two new chronically implantable ultrasonic flowmeters which are designed using unique families of silicon monolithic integrated circuits. Following initial applications in animals, it is conceivable that these implantable flowmeters may be useful in heart surgery patients. For example, by attaching a remotely removable transducer to the aortic wall and connecting it to a subcutaneous electronics package, accurate monitoring of cardiac output might be safely accomplished during the most critical phase of recovery.

CHRONIC PULSATILE BLOOD FLOW MEASUREMENT

The most desirable features of a chronically implantable blood flowmeter are listed in Fig. 1. To begin with, the instrument should exhibit no measurement ambiguity; it should measure a well defined physiological quantity to a specific degree of accuracy. Ideally, it should require no calibration in vitro or in vivo by the user; it should come to him

electronically precalibrated by the producer. During chronic experiments, the instrument should exhibit no significant changes in its baseline or its scale factor. For implantable instruments, small size is an obvious necessity and low power drain is essential to long operating life. To avoid trauma, non-constricting non-erosive flow transducer cuffs are necessary. Finally, to assure full exploitation of an implantable instrument, it should be immediately adaptable to automated data collection.

Electromagnetic Flowmeters For many years the most widely used instrument for measurement of pulsatile blood flow has been the electromagnetic flowmeter [1,2]. Recently a battery operated version of this instrument was announced [3]. The most attractive feature of the electromagnetic flowmeter is that the "flow induced" voltage (e) between its electrodes is proportional to the average velocity of blood ($\bar{v}$) flowing in a circular vessel of lumen diameter (D). Assuming axial flow symmetry and a uniform magnetic field intensity (B)

$$e = [SBD]\,\bar{v} \tag{1}$$

where the sensitivity (S) depends on vessel wall thickness, the tensor conductivity of the wall and the blood conductivity [4]. If the factor (SBD) is known, (1) clearly indicates that the electromagnetic flowmeter provides a measurement of average blood velocity ($\bar{v}$) only; to convert this information unambiguously to instantaneous volume of flow (Q) an entirely independent measurement of lumen diameter (D) is essential since

$$Q = \pi\,(D/2)^2\,\bar{v} \tag{2}$$

Considering the factors which influence S, the product (SBD) can be determined accurately only by the user through in vivo calibration of a given flow transducer via a process such as excising the vessel and collecting a known amount of blood in a given interval of time. Electronic calibration of the instrument is not feasible.

Baseline or zero drift is one of the most difficult problems encountered in electromagnetic flowmeters [2,5]. The principal cause of zero drift in most instances is unwanted voltages induced within the blood and the vessel wall by the sine wave or square wave excitation of the field coils of the flowmeter. To appreciate this problem, one might think of a field coil as an inductor imbedded in a lossy conductive medium consisting of the blood and the vessel wall. Eddy currents induced in this medium by the alternating excitation of the field coil persist for indefinite periods; the potentials they generate between the electrodes of the cuff constitute an unpredictable source of baseline shift which is particularly obscure in chronically implanted transducers. Leakage currents between the field coils and the input electrodes as well as other factors [5] also give rise to baseline shift. Consequently, to establish the approximate baseline necessary

to clamp the vessel at both ends of the flow cuff in order to insure that there is no movement of blood within the cuff. In addition to baseline shifts, scale factor changes may occur during chronic implantation of a flow cuff due to variations in sensitivity (S) resulting from changes in vessel dimensions and tensor conductivity as well as blood conductivity as previously discussed.

Ultrasonic Transit Time Flowmeters The difference in effective velocity of sound pulses propagated alternately upstream and downstream through moving blood is a measure of blood velocity that has been used as the basis of an ultrasonic blood flowmeter [6]. The difference in transit times upstream and downstream is

$$\Delta = \frac{2 L \bar{v}_p \cos \alpha}{c^2} \tag{3}$$

where L is the distance between transducers, $\bar{v}_p$ is the average flow velocity along the path of sound, c is velocity of sound in blood and α the angle between the blood velocity and sonic vectors [7]. An approximation implicit in (3) if it is to be used to describe an actual blood vessel is that the length of the sound path in the vessel wall and surrounding tissue is very small compared to the path length in blood. However, the key factor to recognize is that $\bar{v}_p$ in (3) is not the velocity averaged over the entire lumen area (i.e., $\bar{v}$) but rather the velocity averaged along the linear path of sound between the two transducers. Since various velocity profiles or average velocities $\bar{v}$ may give rise to the same $\bar{v}_p$ there is clearly an ambiguity present in attempting to measure volume flow [8]. consequently, empirical calibration by the user is necessary if one attempts to use this device to estimate volume of flow.

To achieve a practical transit time flowmeter, differences in acoustic transit times on the order of 10^{-10} sec must be measured [9]. This time interval is extremely small and the instrumentation required to measure it tends to be complex, bulky, drift-prone and expensive. Consequently, techniques have been developed for measuring the phase difference $\Delta\phi$ between the upstream and downstream sound pulses [10,11]. In this case, it appears that the baseline or zero flow output of the instrument depends on accurately setting the phase relationships of the two transmitter and receiver channels [11]. This is done initially by adjusting a tank circuit but cannot be checked during implantation when, for example, changes in transducer impedances and hence channel phase shifts cause zero drift.

Continuous Wave (CW) Doppler Ultrasonic Flowmeters A second type of ultrasonic blood flowmeter is based upon the Doppler effect. In this instrument a beam of ultrasonic energy is transmitted through the wall of a blood vessel where it is scattered by the red cells of the bloodstream. The scattered energy which is shifted in frequency according to the Doppler principle, is detected by a second transducer on the opposite

side of the vessel [12,13]. The Doppler frequency shift (f_d) in the scattered ultrasound is given by

$$f_d = f_i - f_s = 2 \frac{v}{c} f_i \cos \alpha \tag{4}$$

where f_i is the incident frequency, f_s the frequency of the scattered sound, v the blood velocity, c the velocity of sound in blood and α the angle between the blood velocity and incident sound vectors. Because blood velocity is a function of radial position within the lumen, (4) represents only a description of the physical principle of operation of the CW Doppler flowmeter and not necessarily its quantitative behavior. The design details of the transducers and the demodulator determine whether this instrument provides an estimate of flow velocity at a particular position or average velocity over the lumen (i.e., volume flow) or neither [14,15].

To measure blood velocity at the center of the lumen the CW Doppler flowmeter transducers should be designed such that the diameter (ΔD) of the volume of intersection of the two transducer beam patterns is small compared with the lumen diameter (D) as illustrated in Fig. 2. In this case v is effectively a constant with the volume of intersection of diameter ΔD and (4) accurately describes f_d as essentially a single line spectrum. Consequently a simple zero crossing demodulator (which in effect computes the second moment of the scattered signal power density spectrum) provides an accurate estimate of velocity at the center of the lumen [14,15]. The benefits to the user of measuring central lumen blood velocity are significant. It is an unambiguous measurement; the measuring instrument can be electronically precalibrated with a high degree of absolute accuracy; and, the measurement is virtually immune to zero drift and changes in scale factor. In addition, estimates of volume flow for a particular vessel can be made by assuming a flow profile and a lumen diameter or by empirical calibration of the instrument.

In contrast to measure volume flow with a CW Doppler flowmeter specifically designed for the purpose, three distinctly different requirements must be met [14,15]:

(1) the entire lumen cross-section must be uniformly illuminated by the transmitting and receiving transducers;

(2) the demodulator must compute the first moment of the power spectral density function of the Doppler shifts SM such that

$$\bar{f}_d = \frac{\int_{-\infty}^{\infty} fS(f)df}{\int_{-\infty}^{\infty} S(f)df} = 2 \frac{\bar{v}}{c} f_i \cos \theta \tag{5}$$

where $\bar{f}_d$ is the average frequency in S(f) and $\bar{v}$ is the average blood velocity; and

(3) lumen diameter must be measured by some independent technique to compute volume flow in accordance with equation (3).

Pulsed Doppler Ultrasonic Flowmeter In principle the pulsed Doppler ultrasonic flowmeter is an elegant extension of the CW Doppler velocity flowmeter. In this instrument a short burst of ultrasonic waves is transmitted through the wall of a blood vessel where it the red cells of the bloodstream. The scattered energy shifted in frequency is detected by the same transducer sure of blood velocity as a function of location within coordinates of each location are derived from the round of the burst of ultrasonic waves from the transducer to return. Therefore, a blood velocity profile can be measured with this instrument. In addition, ultrasonic energy scattered by the walls of the vessel provides the basis for a direct measurement of its lumen diameter. Consequently, the pulsed Doppler flowmeter provides more than sufficient information for an accurate direct measurement of instantaneous volume of flow. Its performance with respect to measurement ambiguities, electronic precalibration, zero drift and scale factor changes is largely equivalent to that of the CW Doppler velocity flowmeter; it is not subject to any inherent shortcomings.

Comparative Features of Flow Telemetry Comparing the various types of flowmeters which have been discussed with respect to measurement ambiguities, electronic precalibration, zero stability and scale factor constancy it appears that the CW Doppler velocity flowmeter and the pulsed Doppler velocity profile or volume flowmeter offer the highest levels of performance. The capabilities of these two instruments although generally desirable are especially attractive for reliable chronically implantable telemetry systems.

Considering size and power drain, the principal difference between the flowmeters under discussion is a consequence of the large (e.g., 500 ma) field currents which are needed in the electromagnetic flow transducer. Typical power requirements for electromagnetic flowmeters exceed 500 mw while those of the implantable ultrasonic flowmeters described hereafter are 10-20 mw. As a consequence of their large field current requirements electromagnetic flowmeters must use relatively sizeable battery packs and cannot be implanted unless provision is made for battery recharging through the skin.

The electromagnetic flowmeter cuff must fit rather tightly around a blood vessel in order to provide good electrical contacts between the vessel wall and the three signal carrying electrodes of the cuff. A looser fit is permitted for ultrasonic flowmeter cuffs since direct contact with the vessel walls is unnecessary; however, proper alignment of the transducers) must be assured. Because it requires only a single ultrasonic element, which

can be mounted in a silastic holder the pulsed Doppler transducer is perhaps the least traumatic of the various flow transducers.

One of the significant advantages which a telemetry system offers in the collection of physiological data is the opportunity to use unanesthetized, unrestrained, undisturbed animals. By providing the telemetry system with an RF controlled switch or command receiver which connects and disconnects the system (flowmeter) electronics to its power supply upon command from a remote control transmitter, automated data collection can take place at all hours of the day while still maintaining a small average power drain. Ultrasonic flowmeters are well suited to this mode of operation.

A CONTINUOUS WAVE VELOCITY FLOWMETER

A block diagram of a chronically implantable CW Doppler ultrasonic flowmeter which measures blood velocity at the center of the lumen is illustrated in Fig. 3 [16-20]. The portion of the system within the dashed rectangle is implanted; the remainder is external. In order to reduce its size and power drain as well as improve its reliability, the implantable portion of this system has been designed to use a unique family of low voltage micropower silicon monolithic integrated circuits. This family consists of four chips: an excitor oscillator circuit for energizing the transmitting transducer; an AM receiver circuit for amplifying and mixing the signal from the receiving transducer; an audio amplifier-FM transmitter circuit for transmitting the telemetry signal; and an RF switch or command receiver for disconnecting the flowmeter electronics from its power source during periods when data is not required. The significance of this family of circuits is that it represents the initial application of a custom family of monolithic integrated circuits to a substantial biomedical instrumentation problem. For this reason some of the unique details of the circuit design are discussed in the following paragraphs.

An additional point of interest regarding the flowmeter illustrated in Fig. 3 is that it measures only the absolute magnitude of local flow velocity and is not sensitive to direction of flow. A CW system capable of sensing both magnitude and direction of flow velocity is under development in the Integrated Circuits Laboratory of Stanford University at this time.

Exciter Oscillator Circuit The schematic diagram of the exciter-oscillator circuit is illustrated in Fig. 4. This circuit consists of a basic Colpitts oscillator, a buffer-driver amplifier and a class C output stage. The design is optimized in several key respects for both monolithic construction and operation from a single Hg cell power source. For example, the collector current of the oscillator transistor Q_3 is set (equal to that of Q_1) by exploiting the virtually perfect match between two adjacent monolithic transistors Q_1 and Q_2 operating transistors Q_3 and Q_4 at OV collector-base voltage eliminates two discrete

(i.e., external to the integrated circuit) bypass capacitors and conserves batter voltage; using direct coupling between Q_6 Q_7 and Q_8 precludes the need for several discrete coupling capacitors; and operating Q_8 with a tuned load permits a collector voltage swing which ideally is twice the supply voltage.

This circuit operates at room temperature over a supply voltage range of 1.0 v to 1.35 v with a frequency stability better than 1%; its current drain is 5ma; it drives the transmitting transducer with a 2 v p-p 6 MHz output voltage at an overall circuit efficiency of 30%; and, it uses six discrete chip components--L_1, C_1, C_2, C_4, C_5 and L_2. Fig. 5 is a photomicrograph of the monolithic circuit fabricated in a 70 x 90 mil silicon die.

Low Noise AM Receiver Circuit A schematic diagram of the low noise AM receiver circuit is illustrated in Fig. 6; the circuit consists of an RF amplifier stage (Q_1 and Q_2); a phase splitter (Q_u and Q_8); and a balanced mixer (Q_3, Q_4, Q_5, Q_6, Q_9, Q_{10} and Q_{11}). Several key features of the design are: close matching of monolithic transistors Q_1 and Q_2 and resistors R_2 and R_3 is exploited in establishing the collector current of capacitor C_2 is a small area monolithic element consisting of emitter junction, collector junction and emitter oxide capacitance in parallel; nevertheless, the resonant frequency of L_1 and C_2 is independent of supply voltage since L_1 maintains a dc voltage of 0 v across C_2; Q_3 and Q_5 are operated at 0 v collector-base voltage and Q_4 and Q_6 are actually operated with a very small forward bias on the collection junction in order to conserve supply voltage. Also, in order to provide equal local oscillator amplitude to both halves (Q_9 and Q_{10}) of the balanced mixer from two points at different dc potentials in the phase splitter (Q_8), the monolithic capacitors C_4 and C_5 consist of emitter oxide capacitance only. Finally, the entire concept of using a balanced mixer is utterly unattractive unless low-cost closely-matched monolithic elements are available. The key advantage of a balanced mixer is that the high level carrier is essentially cancelled by the balanced circuit and does not appear at the audio output. Consequently, filter circuitry to remove the carrier becomes unnecessary; the only discrete components needed in the receiver are C_1 and L_1.

This low noise receiver operates at room temperature over a supply voltage range of 1.0 to 1.35 v. Its current drain is 1.0 ma; its sensitivity is 1.0μv and the conversion gain is 40 dB. Fig. 7 is a photomicrograph of the 70 x 90 mil receiver chip.

Audio Amplifier-FM Transmitter Circuit The schematic diagram of the audio amplifier-FM transmitter circuit is illustrated in Fig. 8. The active transistors in the audio amplifier are Q_3 Q_4 and Q_8; the active transistor in the transmitter is Q_9. The audio amplifier design makes very free use of the unique features of monolithic technology. The large open loop gain (~600) of Q_3 Q_4 and Q_8 is achieved by using high dynamic impedance monolithic lateral PNP transistors (Q_5 and Q_6) as load resistors operating at very low dc voltage drops compared with equivalent conventional resistors. The “push-

pull" connection of Q_3, Q_4, Q_5 and Q_6 results in no loss of gain in the transition from a differential first stage to a single ended second stage. D_1 and D_2 are low forward voltage Al-Si Schottky diodes which serve to establish a suitable collector voltage for Q_2 while conserving supply voltage as much as possible. To avoid oscillation in the audio amplifier it is internally compensated by C_2 which as a Miller capacitance is effectively multiplied by the voltage gain of the second audio stage. Overall negative feedback (R_2) is used to set the closed loop gain of the amplifier. Symmetrical limiting is provided by including Schottky diodes D 14 and D,, in the feedback path. The transmitter is a Colpitts oscillator in the common collector configuration (Q_9) to minimize monolithic parasitic effects at 100 MHz; D_5 is the frequency modulating capacitance.

The audio amplifier-transmitter circuit functions at supply voltages as low as 1.0 v. The amplifier gain is 35 dB, the bandwidth 20 kHz and the effective output voltage swing 0.8 v p-p. The transmitter frequency range is 88-108 MHz. The total current drain of both circuits is 1.5 mA. Fig. 9 is a photomicrograph of the 70 x 90 mil audio-amplifier-FM transmitter chip; in addition to it, three discrete components are used to implement the circuit.

Command Receiver Circuit The final circuit used in the implantable system is the command receiver. Its schematic diagram is illustrated in Fig. 10. This receiver is a tuned radio frequency (TRF) receiver which operates on a single radio frequency. Consequently, there is no need for a local oscillator or an IF amplifier both of which would require discrete inductors and capacitors. Frequency selectivity is accomplished largely by means of a resonant ferrite rod antenna although a discrete ceramic filter element between the RF and detector gain cells can be used to improve selectivity. Essentially, the receiver consists of three stages: an RF amplifier gain cell, an AM detector gain cell and an audio amplifier gain cell. The function of each cell is determined by the collector load resistances and coupling capacitances associated with it. All resistors are high value (125 KΩ - 1.5 MΩ) base pinch resistors; diode biasing is used to conserve power and avoid excessively high value resistors. The receiver design greatly exploits the constant temperature environment within an animal in its use of these later two techniques.

The most remarkable feature of the command receiver is its ultra low power drain of 13μW. This feature is essential since the receiver must operate continuously. Because receiver power drain varies monotonically with radio frequency, a relatively low radio frequency (500 kHz) is used. The modulation frequency is 3 kHz; this permits a further reduction in power drain since much of the receiver gain can be achieved at audio rather than radio frequencies. The overall conversion gain is 70 dB and the sensitivity is 100 μV. The receiver drives a transistor power switch which provides a connection between the flowmeter electronics and its battery power source only during those intervals when a

command signal is present. Fig. 11 illustrates a photomicrograph of the command receiver chip.

A PULSED VELOCITY PROFILE OR VOLUME FLOWMETER

A simplified block diagram of a chronically implantable pulsed Doppler ultrasonic flowmeter which measures blood velocity profile and lumen diameter and hence instantaneous volume of blood flow is illustrated in Fig. 12 [21, 22, 23]. The portion of the system within the upper dashed rectangle is implanted; the lower rectangle contains a block diagram of one channel of an eight channel external system. As with the CW flowmeter, the pulsed system is designed to capitalize fully on the size, power drain and reliability advantages offered by monolithic integrated circuits. Because of the complexity of this system, it is virtually a necessity to implement the implantable portion with integrated circuits specifically designed for the purpose.

As diagrammed in Fig. 12, a novel two-oscillator scheme is used in this particular Doppler system. The 6 MHz ultrasonic oscillator which excites the transducer is synchronized to the 20 kHz oscillator immediately before each transmitted burst of ultrasonic waves. This ensures the necessary phase coherence of the bursts and it is simpler and less powerconsuming than the normal technique of deriving the pulse repetition frequency from the ultrasonic frequency by a series of binary dividers. The transducer emits a 1 μsec burst of sound, then acts as a receiver for the following 49 μsec. The received signal is amplified and phase-detected against the 6 MHz oscillator, with the resulting video signal of 0.5 MHz bandwidth telemetered along with a timing pulse. In the external electronics, multiple range gates with different range settings are used simultaneously to give the instantaneous velocity profile across the vessel.

In the integrated circuit design for this system, emphasis is on low voltage operation and low current drain. To minimize the number of discrete components, two Hg cells are used to give ±1.3 V supply voltages and thus provide three ac ground points in the circuits. The necessary acoustic power is minimized (about 25 mW peak, 0.5 mW average) by transducer and RF amplifier design; the use of a command receiver enables the flowmeter electronics to be switched on only when data is being collected. Due to the need to measure flow velocity at the near wall of the vessel, transducer ringing time following a transmit pulse and receiver overload recovery time are minimized.

An additional point of interest regarding the flowmeter illustrated in Fig. 12 is that it measures the absolute magnitude of the flow velocity profile and is not sensitive to direction of flow. A pulsed system capable of sensing both magnitude and direction of flow profile is now under development in the Integrated Circuits Laboratory of Stanford University.

PERFORMANCE

The instantaneous blood flow velocity in the ascending aorta of a postoperative heart transplant dog is illustrated in Fig. 13. The signal was telemetered with a totally implanted CW velocity flowmeter. The transducer was designed as described in Fig. 2 to respond to blood velocity at the center of the lumen. Referring to equation (4), no calibration was necessary since the frequency (f_1) and the sonic angle of attack (θ) were fixed in the design. An accurate flow zero was obtained by setting f_d equal to zero. Drift in the scale factor was negligible since the excitation frequency (f_i) was stable to within ±1%.

Fig. 14 illustrates the blood flow velocity waveform at the center of the lumen and an eight channel display of the instantaneous blood velocity profile in the descending aorta of an anesthetized dog as recorded with a pulsed Doppler flowmeter.

Although initial tests of the two implantable flowmeters described in this paper have been reasonably encouraging, a substantial effort by a variety of users is needed in order to fully develop the potential of these new instruments.

CONCLUSIONS

Accurate measurement of pulsatile blood flow can be achieved on a chronic basis in research animals through the use of implantable ultrasonic flowmeters. The use of a CW flowmeter to measure flow velocity at a particular location and a pulsed flowmeter to measure velocity profile or volume flow is particularly attractive. Both instruments can be electronically precalibrated and exhibit virtually no baseline or scale factor changes during chronic experiments. Silicon integrated circuits offer significant advantages in reduced size and power drain as well as improved reliability in these instruments. Additional effort is needed to evaluate the instruments and to modify their design to provide a capability for measuring direction as well as magnitude of flow.

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Figure 1. Major desirable features of chronically implantable blood flowmeters.

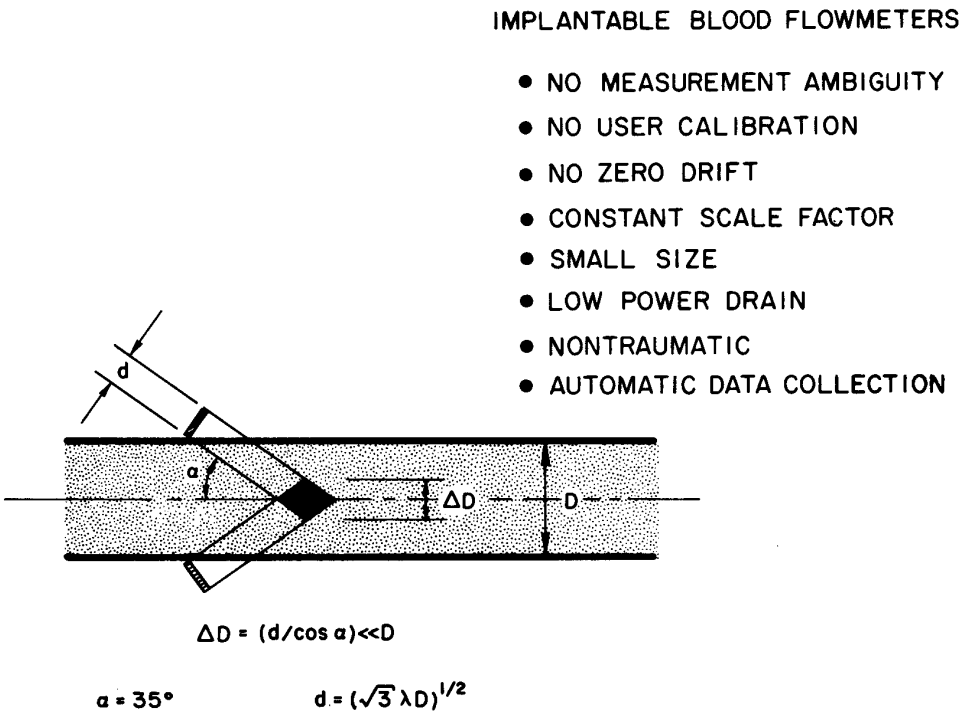

Figure 2. Schematic diagram of CW transducers and beam patterns including condition for measurement of blood velocity at the center of the lumen ($\Delta D << D$) and optimum transducer design ($\alpha = 35°$ and $d = \sqrt{3}\lambda D)^{1/2}$) for meeting this condition [14].

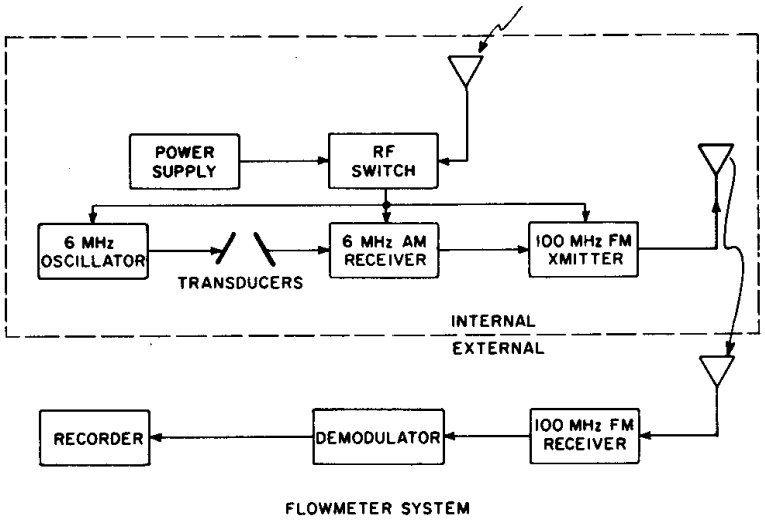

Figure 3. Block diagram of implantable CW Doppler flowmeter.

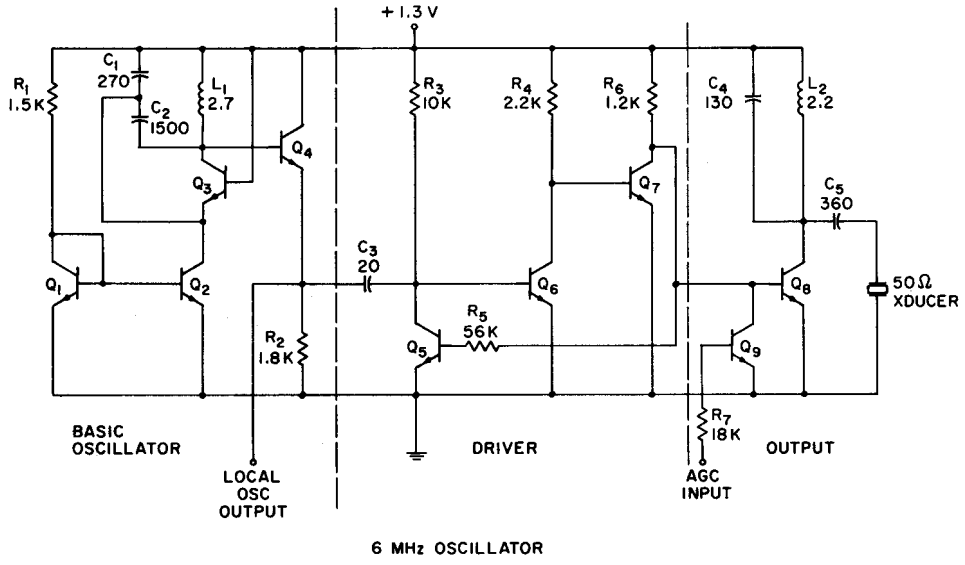

Figure 4. Schematic diagram of CW exciter-oscillator circuit.

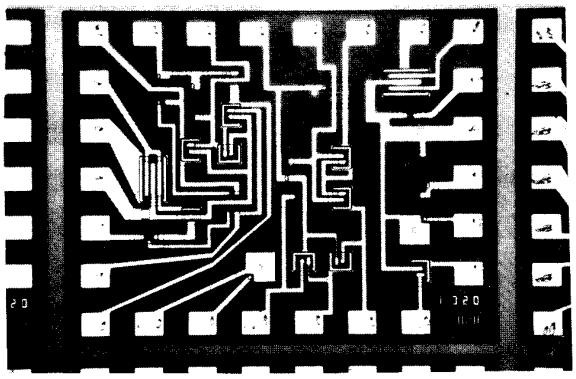

Figure 5. Photomicrograph of exciter-oscillator chip before die scribing and wire bonding.

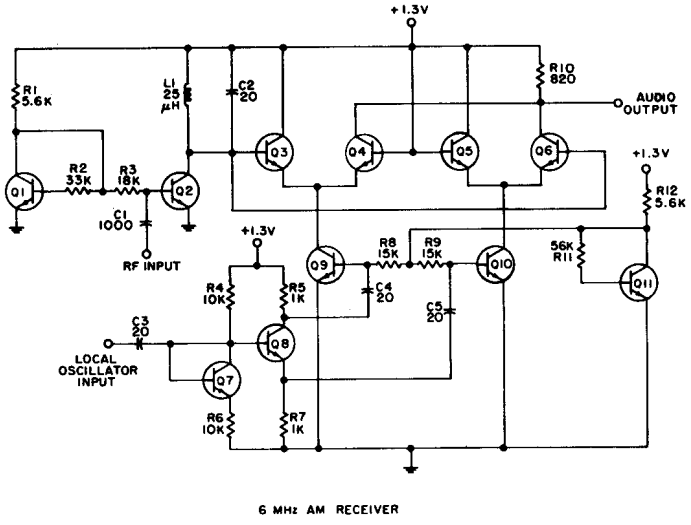

Figure 6. Schematic diagram of low noise AM receiver circuit.

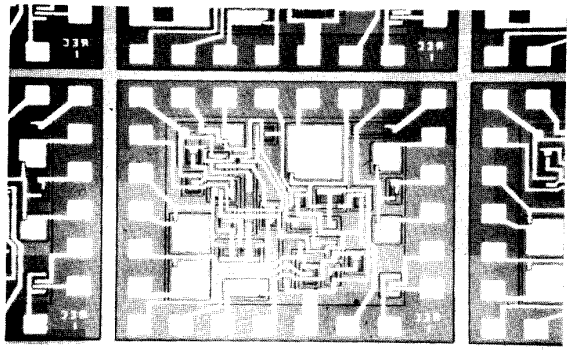

Figure 7. Photomicrograph of AM receiver chip.

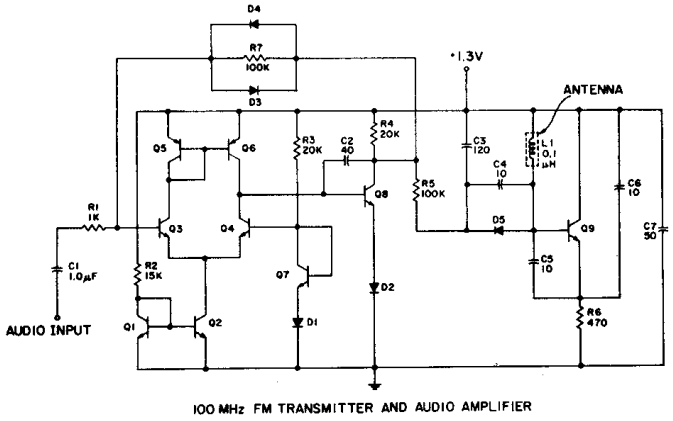

Figure 8. Schematic diagram of audio amplifier FM transmitter circuit.

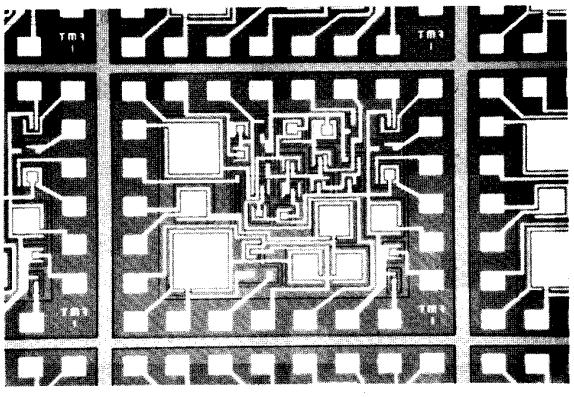

Figure 9. Photomicrograph of audio amplifier-FM transmitter chip.

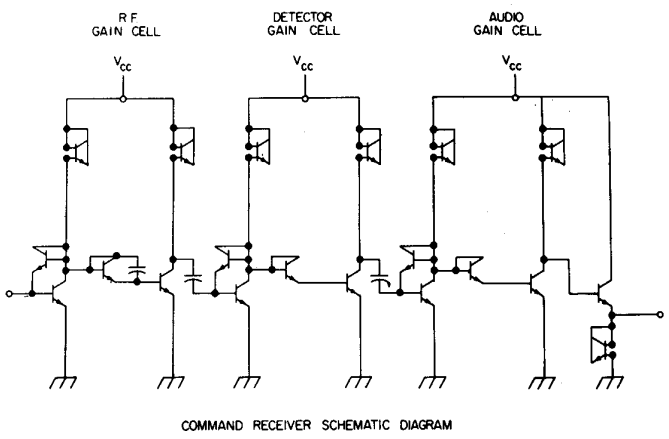

Figure 10. Schematic diagram of command receiver.

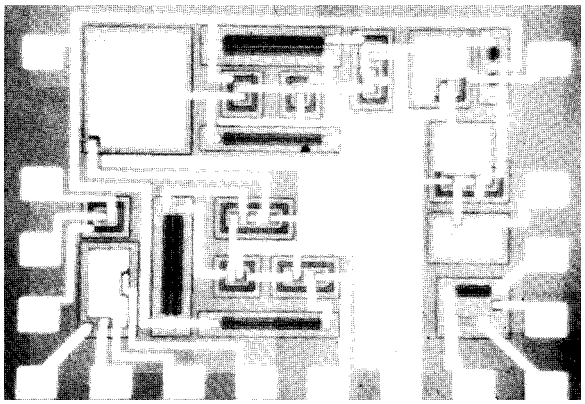

Figure 11. Photomicrograph of command receiver chip.

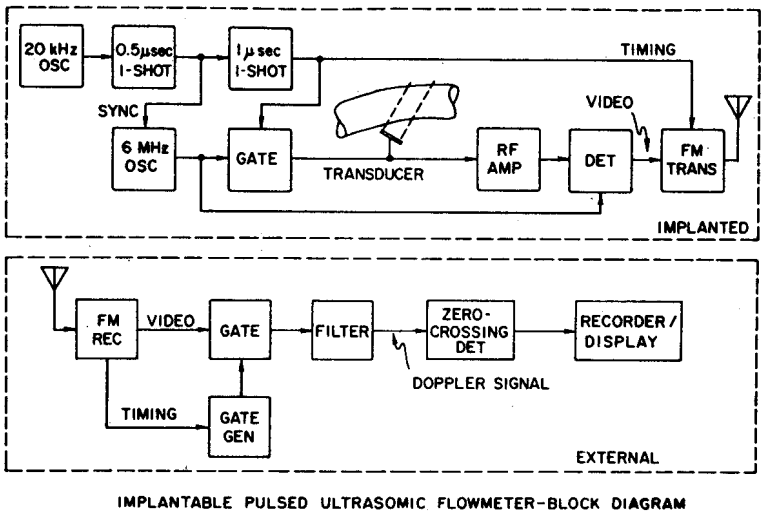

Figure 12. Block diagram of implantable pulsed Doppler flowmeter.

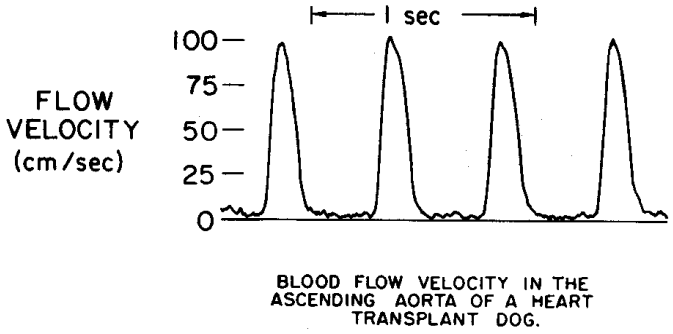

Figure 13. Blood flow velocity waveform recorded with the CW Doppler flowmeter

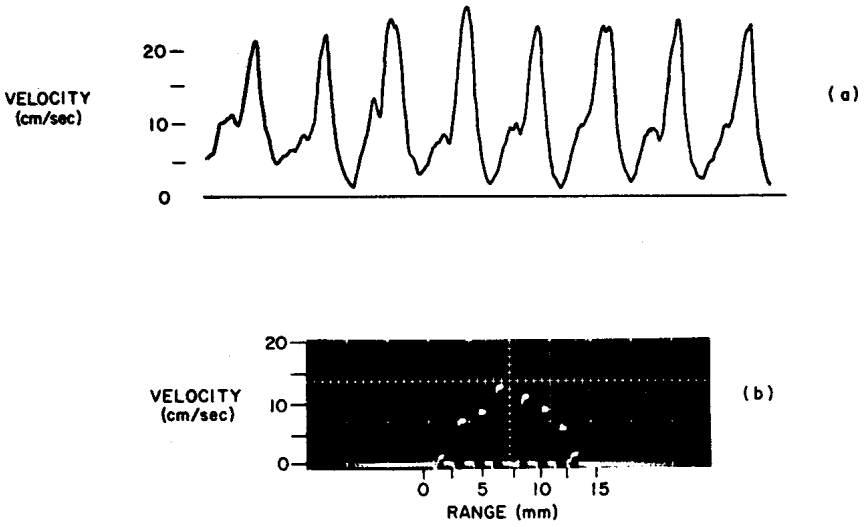

Figure 14. Blood flow velocity waveform and velocity profile recorded with the pulsed Doppler flowmeter.