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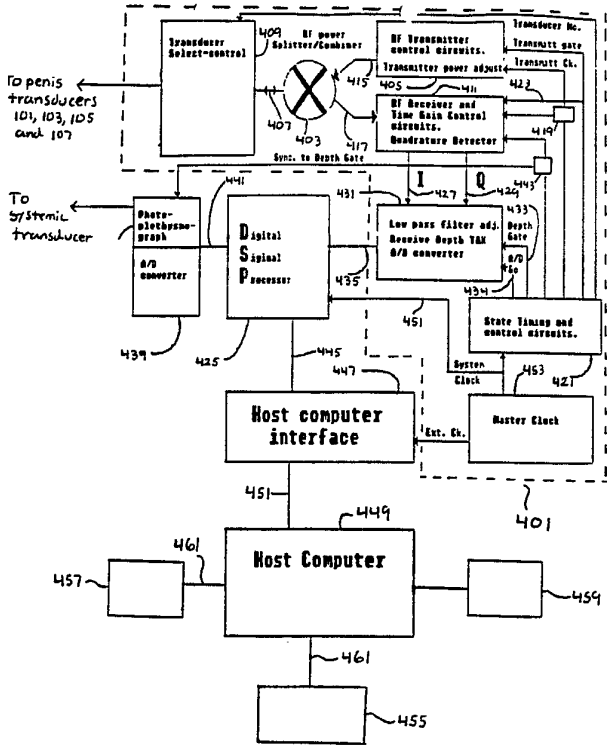
(54) Title: APPARATUS AND METHOD FOR SENSING ERECTILE FUNCTION

(57) Abstract

An apparatus and method for sensing and measuring penile blood flow wave forms and for evaluation of penile erectile function based on these wave forms is disclosed. Noninvasive sensors such as piezoelectric pulse wave transducers or pulse sensors such as piezoelectric pulse wave transducers or pulse oximetry transducers (103, 105, 107) are attached to the penis and developed electrical signals representing penile blood flow wave forms. These electrical signals are conditioned by a digital signal processor (slave) (401) and a host computer (master) (449) and associated programs. The penile blood flow wave form conditioning includes comparison of the subject's real time penile blood flow wave form with reference penile blood flow wave forms stored in memory to yield the penile erectile function based on penile erection phase, penile blood flow systolic and diastolic velocities, penile intracorporal pressure, penile intracorporal resistance and/or penile blood oxygenation. These values and wave forms are displayed on a monitor and saved on an archive device for future play back.



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APPARATUS AND METHOD FOR SENSING ERECTILE FUNCTION

BACKGROUND OF THE INVENTION

This invention relates to instrumentation for sensing and measuring penile blood flow wave forms and for the evaluation of penile erectile function based on these wave forms.

The penis is divided into four hydraulic chambers; two corpora cavernosa, a corpus spongiosum, and a glans. Although all contain spongelike sinusoidal tissue, only the corpora cavernosal sinusoids contain the venous sinusoidal occlusion mechanism. By permitting blood to flow into but not out of the corpus cavernosum, the venous sinusoidal mechanism can transform the corpus cavernosum from an open to a closed chamber capable of trapping blood and thus producing rigid erections. Under normal circumstances, each corpus cavernosum is supplied by its own cavernosal artery. Cavernosal artery flow and pressure determine the competence of the erectile process. The dorsal and bulbar arteries supply blood to the skin of the penis, glans, and corpus spongiosum, playing only a minor role in the erectile process.

The erectile cycle can be divided into four phases: initiation, generation, maintenance, and detumescence. The earliest phase of erection, initiation, occurs when a neurochemical stimulus causes a rapid inflow of arterial blood into the corpora. The sinusoids become engorged. Generation occurs when the venous outflow mechanism closes. Blood is then stored in the corpora cavernosal bodies. The

penis expands until full rigidity is achieved. Maintenance occurs when the corporal bodies are fully expanded and the arterial inflow and venous outflow are in an equilibrium state such that full penile expansion and pressure are maintained. Detumescence is the process whereby full erection is lost by either a decrease in arterial inflow or an increase in venous sinusoidal outflow. These erection phases can be characterized by the shape of their cavernosal blood flow wave forms.

Erectile dysfunction, impotence, can be caused by physiologic or psychologic factors. Normal erectile function requires adequate penile arterial inflow, sufficient corpora cavernosal expansion, and competent venous sinusoidal outflow occlusion. Severe malfunction of any one of these components, or a cumulative failure of multiple components, will result in erectile failure. Improved medical and surgical treatment of impotence has made it necessary to access erectile physiology more accurately in order to determine which vascular component is dysfunctional and to distinguish whether a patient suffers from a phychologic or physiologic etiology for his impotence.

In order to diagnose the underlying cause of erectile failure, it is necessary to define which vascular element is dysfunctional. Since the vascular events are dynamic, changing with each phase of erection, it is important to correlate vascular physiology with each phase of erection of defining vascular physiology and cannot assign a physiologic cause in a patient who fails to achieve erection.

The first category of devices measures mechanical penile events. These function by determining the rigidity or circumference of the penis. These devices most frequently measure the degree of erections a patient develops at night time during REM sleep. These devices are useful in defining whether a patient can or cannot generate a normal nighttime erection. These devices are incapable of defining vascular physiology, and cannot assign a physiologic cause in a patient who fails to achieve erection.

The second class of devices available can define vascular physiology. However, these devices require a technician to operate them and an injection of medication into the penis is necessary in order to induce erections and perform these tests. These tests are usually performed in the doctor's office while the patient is awake, and they require constant observation by a physician or technologist during interrogation of penile vessels. These tests are both invasive and expensive to the patient.

Since generation of erections involves a complex balance between psychologic and physiologic events, a patient's ability to have a normal erection may be inaccurately diagnosed in the doctor's office due to the inhibition a patient may experience because of the embarrassment when attempting to develop an erection in an office setting in front of other individuals, because of the pain of an injection into the penis, or because the technician or physician is unable to observe the patient throughout the study. As a result of these limitations, inaccurate

diagnoses of the patient's erectile capacity are known to occur. Secondarily, inaccurate diagnoses may cause a patient to be subjected to unnecessary surgeries or interventional procedures.

During the past decade, improved medical and surgical treatment of organic impotence has made it necessary to assess erectile physiology accurately. Unfortunately, to date it has not been possible to provide an inexpensive, noninvasive, comprehensive method for reliably determining normal and abnormal erectile function while at the same time assessing erectile physiology in the dysfunctional patients.

SUMMARY OF THE INVENTION

The present invention provides an apparatus and method for sensing and measuring penile blood flow wave forms, and for processing and evaluation of these wave forms to diagnose and categorize penile erectile function or dysfunction.

Electrical signals representing penile blood flow wave forms are developed by non-invasive sensors. These sensors preferably are Doppler piezoelectric transducers. In an alternate embodiment, these sensors can be pulse oximetry and/or photoplethysmographic transducers in addition to, or instead of, Doppler piezoelectric transducers.

The electrical signals representing penile blood flow wave forms are processed by a digital signal processor (slave) and are then transferred to a host computer (master) where they are compared to normal and/or abnormal reference penile blood flow wave forms stored in memory. This

processing and comparison by the digital signal processor and host computer yields the subject's penile erectile function based on penile erection phase, penile blood flow systolic velocity, penile blood flow diastolic velocity, penile intracorporal pressure, penile intracorporal resistance, and penile blood oxygenation.

In a preferred embodiment, these values and wave forms are displayed on a monitor.

In another preferred embodiment, these values and wave forms are printed to create a patient report.

In another preferred embodiment, these values and wave forms are stored on an archive device for future playback.

In another preferred embodiment, the noninvasive sensors, digital signal processor, and associated memory are separable from the host computer for data gathering outside of the clinical environment.

In another preferred embodiment, a systemic (non-penile) blood flow wave form is non-invasively sensed with oximetry or photoplethysmographic transducers. The subject's own real time systemic blood flow wave forms, in addition to or instead of reference penile blood flow wave forms, are thus compared to the subject's penile blood flow wave forms by the digital signal processor and host computer to yield penile erectile function.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features of the present invention will be more fully appreciated when considered in the light of the following specification and drawings in which:

FIG. 1 is a perspective view of the penile transducers of the present invention.

FIG. 2 is a cross-section of the penile transducers of the present invention taken at line 2-2 of FIG. 1.

FIG. 3 is a cross-section of the penile transducers of the present invention taken at line 3-3 of FIG. 1.

FIG. 4 is a block diagram of the apparatus for measuring penile blood flow wave forms and for evaluation of penile erectile function.

FIGS. 5a, b, c, and e are schematics of the electronic circuitry of the wave form collecting and processing components of the present invention.

FIG. 5d is a flow chart depicting the programming of the state timing and control circuits.

FIG. 6 is a flow chart of the host computer examination program.

FIG. 7 is a flow chart of the host computer examination loop subroutine.

FIG. 8 is a flow chart of the event recording loop subroutine.

FIG. 9 is a flow chart of the digital signal processor Doppler flow examination program.

FIG. 10 is a flow chart of the Doppler data processing subroutine.

FIG. 11 is a graph of Doppler penile blood flow wave forms of erectile phase 0.

FIG. 12 is a graph of Doppler penile blood flow wave forms of erectile phase 1A.

FIG. 13 is a graph of Doppler penile blood flow wave forms of erectile phase 1B.

FIG. 14 is a graph of Doppler penile blood flow wave forms of erectile phase 2.

FIG. 15 is a graph of Doppler penile blood flow wave forms of erectile phase 3.

FIG. 16 is a graph of Doppler penile blood flow wave forms of erectile phase 4.

FIG. 17 is a graph of Doppler penile blood flow wave forms of erectile phase 5A.

FIG. 18 is a graph of Doppler penile blood flow wave forms of erectile phase 5B.

FIG. 19 is a graph of Doppler penile blood flow wave forms of a male having abnormal penile arterial function.

FIG. 20 is a graph of Doppler penile blood flow wave forms of a male having abnormal penile venous function.

FIG. 21 is a graph of Doppler penile blood flow wave forms of a male having abnormal penile arterial and venous function.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Penile Wave Form Transducers

Referring to FIGS. 1-3, the apparatus for sensing and measuring penile blood flow wave forms and for evaluation of penile erectile function includes transducers 101, 103, 105 and 107 circumferentially located around the shaft of the penis 109. In the embodiment described, transducers 101, 103, 105 and 107 are Doppler pulse wave transducers.

However, transducers 101, 103, 105 and 107 may also be pulse oximetry transducers known in the art that sense penile blood oxygenation based on the frequency of the transducer-transmitted light waves that are absorbed by the hemoglobin of the penile blood. The pulse oximetry transducers may be employed either in addition to, or instead of, Doppler piezoelectric transducers. Additionally, these transducers can be photoplethysmographic transducers known in the art.

Doppler transducers 101, 103, 105 and 107 are piezoelectric ceramic composite transducers preferably sized and shaped to transmit preferably at 7.5MHz or 10MHz, or a range therebetween. Transducers 101, 103, 105 and 107 are preferably secured in a synthetic elastomeric polymer condom-like sheath 111 that is less restrictive than a normal condom so that erectile function is not impeded. Alternatively, a condom-like sheath of woven material, either with or without elastomeric properties, may be employed. Adhesives may also be employed to secure sheath 111. In an alternative embodiment, the transducers 101, 103, 105 and 107 can be

secured to the penis 109 with an adhesive alone. The above descriptions of the securing of transducers 101, 103, 105 and 107 are exemplary only, and are not intended to be exhaustive.

Electrical leads 113 connect the transducers 101, 103, 105 and 107 to transducer select-control circuit 409, described below, that sequences the sensing of transducers 101, 103, 105 and 107 such that only one transducer provides penile blood flow wave form data at any given time. The Doppler sensing by tranducers 101, 103, 105 and 107 is thus sequenced to allow real time Doppler detection of penile blood flow wave forms.

The preferred number of transducers 101, 103, 105 and 107 is four, however, a fewer or greater number may be employed. When four transducers 101, 103, 105 and 107 are employed, as shown in FIG. 2, these transducers are preferably circumferentially oriented such that transducers 103 and 107 are located in the dorsal region of penis 109, nearer to transducer 105 than to transducer 101.

Referring still to FIGS. 1 and 2, the penis 109 includes glans 115, two corpus cavernosa 201, cavernosal artieries 203, dorsal veins 205, dorsal arteries 207, bulbo spongiosum 209, sinusoids 211, and bulbo-urethal artery 213.

Referring to FIG. 3, one of transducers 101, 103, 105 and 107 is shown. Note that in one embodiment the transducer, in this case 105, is oriented on penis 109 such that transducer elements 301 and 303 are oriented at a fixed angle relative to cavernosal artery 203 by wedge 305. This

angular orientation of transducers 101, 103, 105 and 107 allows a Doppler estimate of the angle 0. The angle 0 is required to calculate the velocity of blood flow relative to Doppler frequency W_d based on the following equation:

$$W_d = \left(\frac{2v}{c}\right) W_{tx} \cos 0 \qquad (1)$$

where W_d = Doppler frequency (radians)
v = velocity of blood flow
c = speed of sound in human tissue
W_{tx} = transmitter frequency (radians)
θ = angle of transducer orientation
cos = $\frac{\text{adjacent}}{\text{hypotenuse}}$

The angle θ can be calculated, referring to FIG. 3, based on the following equations:

$$\cos\theta = \frac{a}{d} \qquad (2)$$

$$= \frac{a}{\sqrt{a^2 + f^2}} \qquad (3)$$

$$= \frac{a}{\sqrt{a^2 + (d-c)^2}} \qquad (4)$$

where c and d = the Doppler depths measured by transducer elements 301 and 303

a = the fixed distance between transducer elements 301 and 303

Thus, as explained in detail below, the wave form collecting and processing apparatus of the present invention solves for cosine θ based on equation 4 where a is a known distance and c and d are transducer measured distances. Then, the cosine θ value from equation 4 is employed in equation 1 to solve for the velocity of the blood flow v relative to Doppler frequency W_d.

It is readily apparent, however, that other methods of ultrasound acquisition besides Doppler ultrasound known in the art may be employed.

Systemic Wave Form Transducers

The apparatus for measuring penile blood flow wave forms and for evaluation of penile erectile function optionally includes systemic wave form transducers (e.g., photoplethysmography or oximetry sensors known in the art) to measure the subject's systemic (as opposed to penile) blood flow wave forms. These systemic wave form transducers preferably sense blood flow at the subject's finger or ear. The systemic blood flow wave forms, as discussed below, are subsequently processed by the digital signal processor 425 and host computer 449, and compared to the subject's own real time penile blood flow wave forms. This comparison may be in addition to, or instead of, the comparison of the subject's penile blood flow wave forms with reference penile blood flow wave forms stored in host computer memory.

Wave Form Collecting and Processing Apparatus

Referring to FIGS. 4 and 5a-d, the apparatus for collecting and processing penile blood flow and systemic blood flow wave forms is now described.

Referring to FIG. 4, RF power splitter/combiner 403, RF transmitter control circuits 405, transducer select control circuit 409, RF receiver and time gain circuits 411, state timing and control circuits 421, receive depth track and hold

amplifier and analog to digital converter 431, and master clock 453 comprise wave form collecting and processing components 401 further detailed in FIGS. 5a-d.

A. RF Power Splitter/Combiner

Referring now to FIG. 4, the radio frequency power splitter/combiner circuit 403 of wave form collecting and processing components 401 receives the transmitter RF burst from RF transmitter control circuits 405 and impedance matches the transmit burst to the active transducer elements 101, 103, 105, and 107 by passing the signal out the coaxial cable 407 to the transducer select-control circuit 409. The RF receiver and time gain control circuits 411 are impedance matched by the splitter/combiner 413 such that, during transmit, the load presented by the connector 417 is high, thus preventing transmitter power loss from connection 415 into connection 417 and into RF receiver gain control circuit 411. The coaxial cable 407 of the power splitter/combiner 403 matches the characteristic impedance of the active transducer elements 101, 103, 105, and 107 for both transmit and receive. The circuitry of power splitter/combiner 403 employs steering diodes and blocking diodes in combination with RF transformer coupling, designed to match the characteristic impedances of each individual port of power splitter/combiner 403.

B. RF Transmitter Control Circuits

The RF signal used to develop the acoustic energy transmitted by the active transducer elements 101, 103, 105,

and 107 is produced by RF transmitter control circuits 405. The transmitter clock 419 is provided by the state timing and control circuit 421. The frequency of this clock would range between 5.0 MHz and 10.0 MHz. Optimally, the frequency of this signal will be 7.5 MHz or 10 Mhz. The RF transmitter and control circuits 405 will logically 'and' the transmit clock 419 with the transmit gate 423 to generate a gated RF burst of 4 cycles of a 7.5 MHz clock to give a theoretical depth resolution of approximately 1/2mm, and a practical resolution of 1mm depth discrimination.

The digital signal processor 425 sets the transmit power level. This circuit sets the high voltage applied to the transmit output drive circuit. The selection of a power level is done by direct digital control, such as a digital to analog converter to a high voltage regulator bias circuit.

C. RF Receiver and Time Gain Control Circuits

The RF receiver and time gain control circuits 411 are impedance matched to the input signal connection 417. To protect the RF-preamplifier, the signal present on connection 417 is clipped at a diode conduction potential (i.e., 0.6V). The second stage of RF gain is used to amplify the input signal on connection 417 to a level approximately +60dB. The signal is split into two identical RF signals with significant protection against cross coupling of a signal energy. In addition, an increase of RF gain with increasing time, relative to transmit, will compensate RF signal

attenuation due to energy absorption by the body tissue of the applied transmit burst.

The two isolated amplified RF signals are down converted to detect useful Doppler information. The detection can be performed by sampling the RF signal at the frequency of the transmit clock 419. The transmit clock 419 is used to detect the Doppler signal content in one of the two isolated amplified RF signals. The second isolated amplified RF signal is mixed against a 90 degree phase shifted version of the transmit clock 419. By using a clock 419 as a reference input clock, and by using a 90 degree phase shift of clock 419, the character of the Doppler information is preserved in the recovered audio bandwidth Doppler signals 427 and 429. A quadrature detector preserves a lead/lag relationship in the detected signals. The lead/lag relationship of the signals allows the digital signal processor 425 to discriminate between a UP Doppler shift (blood flow toward the transducer), and a DOWN Doppler shift (blood flow away from the transducer). Mixing and low pass filtering converts the Doppler signal inputs at connection 417 (into RF receiver and gain control circuit 411) to the audio bandwidth Doppler signals 427 and 429.

The corner frequency (cut-off frequency) of the low pass filters used to receive the audio bandwidth Doppler signals 427 and 429 must be as low as possible to eliminate aliasing of out-of-band signals, as well as to reduce the noise bandwidth of the recovered Doppler information. However, it is necessary to maintain sufficient signal

bandwidth in the recovered bandwidth Doppler signals 427 and 429 to discriminate between signals arriving from different anatomical depths in the body. Discriminating Doppler data received to within a 1mm depth of anatomical origin requires a low pass filter that is matched to the RF transmit burst.

An adjustable low pass filter allows the digital signal processor 425 to determine the depth of the blood vessel in order to correctly determine the angle 0 of the transducer 101, 103, 105 and 107 relative to the blood vessel examined. This Doppler angle correction is discussed in further detail above in conjunction with the description of transducers 101, 103, 105 and 107, and below in conjunction with the discussion of the wave form collecting and processing apparatus operation. Once the Doppler angle is determined, the cut-off frequency of the low pass filter can be lowered to reduce the noise bandwidth of the RF receiver and time gain control circuits 411. The anatomy of the penis dictates that no Doppler interference of the vessel blood flow occurs by loss of depth discrimination for the transducer elements 103, 105 and 107. Because the transducer 101 is located in close proximity to multiple blood vessels, this element 101 does not have its associated low pass filter bandwidth decreased. The ability of the transducer to discriminate between multiple vessels and their associated Doppler signal prevents reducing the low pass filter's corner frequency.

D. Receive Depth Track and Hold Amplifier (T&H) and A/D Converter

The Doppler signal depth detection is accomplished by a track and hold (T&H) amplifier and analog to digital converter 431. The time delay of the amplifiers signal 'hold' is determined by the depth gate 433. State timing and control circuitry 421 generates the depth gate 433 in increments of 1.25 microseconds; this time represents 1mm of sound travel in the acoustic model of body tissue. The digital signal processor 425 is responsible for positioning the depth gate over the region of maximum blood flow. Once positioned over the region of maximum blood flow, the position of the 'hold' gate of receive depth track and hold amplifier and analog to digital converter 431 will remain constant, allowing the digital signal processor 425 to perform pattern recognition algorithms on the Doppler received signal. The signal 'held' by the T&H amplifier is sampled by the A/D converter of 431 and is synchronized by the A/D GO pulse 434 that is generated by the state timing and control circuit 421. This digital representation of the analog receiver's Doppler signal content corresponds to the acoustic Doppler energy of the blood cell scatter in the sample volume, 1mm in size, at a depth in the body determined by the depth gate 433. Once the analog data is in digital format, the data is passed to the digital signal processor 425 on the A/D interface bus 435.

The signals 427 and 429 must be simultaneously sampled by the T&H amplifier of 431. The simultaneous

sampling preserves the phase relationship of the signal 427 relative to signal 429. This information is required by the digital signal processor 425 in order to resolve blood flow direction relative to the transducer 101, 103, 105 and 107. The A/D converter of 431 can be multiplexed between the analog 'held' signal output of the T&H amplifier of 431 or separate A/D converters can be used to sample the T&H outputs independently. The essential feature is the preservation of the phase information of signal 427 and signal 429 in the digital data passed to the digital signal processor 425 on the analog interface bus 435.

E. Systemic Wave Form Signal Processing

The use of a standard systemic wave form measurement device 437, such as a photoplethysmograph equipped with an A/D converter 439 to digitize the detected flow output, provides additional information to digital signal processor 425. The systemic flow wave form of blood flow (in the hand or ear of the subject patient) is correlated by the digital signal processor 425 to the blood flow wave form of the penis. The digital systemic blood flow data is passed to the digital signal processor 425 on the interface bus 441. A penile depth gate sample marker 443 is used to encode the digital data passed on the interface bus 441 from the A/D converter 439. This marker allows the digital signal processor 425 to synchronize, in time, the flow data from transducers 101, 103, 105 and 107 on the penis and systemic blood flow transducer on the hand or ear.

F. Digital Signal Processor (DSP)

The digital signal processor 425 is a slave computer designed for mathematical calculations of Fast Fourier transforms, autocorrelation, crosscorrelation, IIR (Infinite Impulse Response) filters, FIR (Finite Impulse Response) filters, amongst others. Digital signal processor 425 preferably includes a slave central processor unit chip which may be the "DSP 32C" chip manufactured by American Telephone and Telegraph, Inc., or the "TMS 320C25" chip manufactured by Texas Instruments, Inc. Digital signal processor 425 also includes a random access memory and has buffer chips and control logic known in the art. The digital signal processor 425 controls the depth position of the active transducer 101, 103, 105 or 107 with depth gate 433. Digital signal processor 425 sequences the active transducer elements 101, 103, 105 or 107 positioned on the penis, as well as managing the interface bus 441, A/D interface bus 435, and host computer communication bus 445. The digital signal processor algorithms (detailed below) analyze the Doppler flow information and make use of spectral evaluation of flow to correlate the subject penile blood flow wave form data to that of normal penile blood flow wave form data. Both raw data and processed, analyzed data is stored in a RAM memory in digital signal processor 425 and, after a predetermined data collection time period, can be passed to the host computer 449 over the host interface bus 445 for further processing.

G. Host Interface Bus

The host interface bus 451 allows system synchronization between the host computer 449, digital signal processor 425, and master oscillator timing 451 from master clock 453. The time critical nature of real-time signal processing is greatly enhanced by synchronizing all system components to a single master clock 453. Master clock 453 and state timing and control circuits 421 produce coherent digital noise. Coherent noise can be effectively processed by the digital signal processor 425 without degrading the analog Doppler signal information. Asynchronous digital noise can cross modulate with analog signals to produce false Doppler information. Once false Doppler modulation is injected into the analog signal path, it is difficult for the digital signal processor 425 to discriminate Doppler data sensed by transducers 101, 103, 105 and 107 from the false Doppler data.

H. Host Computer and Peripherals

The host computer 449 (central processing unit, ROM, RAM) is responsible for user interface. The data processed by the digital signal processor 425 is displayed on monitor 455. Essential penile blood flow wave form data is saved in archive device 457 (e.g., hard disk drive, optical disk drive, magnetic tape drive, or floppy drive). A printer 459 creates permanent wave form data records. The monitor

455, archive device 457, and printer 459 are connected to the host computer 449 on standard interface busses 461.

With a portable, patient mounted system, the digital signal processor 425 and associated wave form collecting and processing components 401 can be disconnected from host computer 449 at the host interface bus 445 for more convenient subject examination. The digital signal processor 425 and associated wave form collecting and processing components 401 can thus perform the Doppler blood flow signal processing independent of host computer 449, and are subsequenctly reconnected to the host computer 449 through host computer interface bus 445. When separable at the host interface bus 445, the data storage device 457 is modified. With digital signal processor 425 operating independent of the host computer 449, the data storage device 457 to is connected directly to the digital signal processor 425 so that all data is recorded as permanent record of the subject's blood flow wave forms. A complete record of all spectral data is needed to allow physician review of the entire examination.

I. Electronic Circuitry of Wave Form Collecting and Processing Components

Referring now to FIGS. 5a-d, the electronic circuitry of wave form collecting and processing components 401 is described.

Referring to FIG. 5a, the transducer elements 101, 103, 105 and 107 are standard ceramic piezoelectric elements. These piezoelectric elements are individually attached to

relays 501, 503, 505 and 507. The transformers on the output of each relay to the individual transducer elements transform the capacitive load of the transducer element to a 50 ohm real impedance and connect to the relays in the transducer select-control circuits 409. The transducer select signal 509 energizes a single relay switch. The choice of which transducer is enabled is digitally determined by the digital I/O control circuit of digital signal processor 425. The transducer selection is determined by an acquisition software program in the digital signal processor 425.

The output of the select-control circuits 409 is directly connected to the power splitter/combiner 403. The power splitter/combiner 403 impedance matches the transmitter output drive to the ceramic piezoelectric crystal selected. Also, the power splitter must impedance match the amplifiers of the RF receiver and time gain control circuits 411 input impedance to the active transducers 101, 103, 105 and 107. Note that the transducers 101, 103, 105 and 107 are attached electrically to the RF receiver and time gain control circuits 411 and the RF transmitter control circuits 405, but the RF receiver and time gain control circuits 411 are isolated from the RF transmitter control circuits 405. Blocking diodes in the transmitter output drive make the RF transmitter control circuits 405 appear to be a high impedance to the RF receiver and time control circuits 411 except when actually transmitting. When transmitting, the RF receiver and time gain control circuits 411 are not functional, and the shunting diodes on the input of the

receiver protect the receiver's input circuit from the high voltage developed during transmit.

The receiver input transformer 511 boosts the RF signal as well as isolates the RF receiver and time gain control circuits 411 from the transmission line 417. The bias power of the RF receiver and time gain control circuits 411 is indicated by +v and -v. RF pre-amplifier 513, an N channel JFET, is used for RF gain. The common collector amplifier 515 impedance matches the output of the RF pre-amplifier 513 to the input of TGC amplifier 517. TGC amplifier 517, a dual gate MOSFET, has the RF signal applied to the 'signal-input', gate-1, and the gain bias voltage applied to gate-2. The gain bias voltage is developed by the TGC digital-to-analog converter and filter circuit. This voltage is increasing the time from off at transmit in order to blank the transmit burst to a maximum voltage gain at the depth of the receiver gate.

Emitter amplifier 519 isolates the drain output of TGC amplifier 517 from the RF channel-splitter-transistors 521 and 523. RF-1 and RF-2 signals are identical in phase and amplitude. The processing of these signals is continued in FIG. 5b. Similarly, the transmitter signal path is described in FIG. 5d.

Referring to FIG. 5b, the signals RF-1 and RF-2, are synchronously sampled by RF channel-splitter-transistors at a sample clock of the same frequency as the RF component of the transmitter burst. RF channel-splitter-transistor circuitry 523 samples signal RF-2. An identical circuit 521

(not shown) to 523 samples signal RF-1 with a 90 degree phase shift. In the present embodiment, the transmitter is 7.5MHz. The sampler signal is applied to circuit 525 under control of the state timing and control circuits 421. The phase of the sample clock used to select 525 is identical to the transmit clock. But, the signal used to select 521 is phase shifted by 90 degrees to preserve the lead-lag nature of the Doppler detected signal.

The detected Doppler signal is coarsely filtered and buffered by buffer amplifier 527. Fixed gain amplifier 529 is used for additional gain prior to the low pass filter. The essential features of the low pass filter are 72dB of dynamic signal range from the pass band to the stop band, and signifcant anti-alias filtering of the low pass filter's internal clock to prevent degrading the Doppler signal that is processed by the low pass filter.

The opto-isolation circuit 531 in the digital path between digital signal processor 425 and the low pass filter of 431 is used to suppress digital noise from digital signal processor 425. The isolation is needed to prevent the degradation to the Doppler signal path by digitally modulated noise currents. A second opto-isolation circuit 533 is located between digital signal processor 425 and state timing and control circuits 421.

The audio band-width outputs I and Q contain the detected Doppler signal. The phase relationship of I to Q indicates the blood flow direction of the detected signal

relative to the transducer element. The further processing of these signals is indicated on FIG 5c.

In FIG. 5c, the Doppler detected signals I and Q are sampled at a time delay from transmit that corresponds to the round trip speed of sound in a penis tissue of sample depth D. This time delay is the depth gate, generated by the state timing and control circuit 421. For proper signal processing, the simultaneous depth sample signal is held in the track and hold amplifier 535 of receive depth track and hold amplifier and analog/digital convertor 431. The held signal levels are multiplexed to the output amplifier and converted by the A/D converter 537 of 431. The PRF (pulse repetition frequency) of the transmitter determines the rate the depth gate is sampled. One receive signal pair is processed per transmit burst. The PRF is of sufficient duration to allow the round trip propagation of the transmit burst relative to the blood vessel examined. This PRF timing can be fixed for a maximum usable signal depth, or adjustable, based on the depth needed to sample a specific vessel. If PRF is made adjustable, the detected Doppler shifted signal is compensated based on the PRF used at any specific depth. If the PRF is fixed, the Doppler shift is determined 'constant' for all depths evaluated. The present embodiment employs a fixed PRF for all depths.

The state timing and control circuits 421 has a timing circuit that is a logic sequence. The timing of the logic sequence is determined by the resolution required in the Doppler detected signal. The logic sequence is driven by

master clock 453. The specific implementation to this circuit is realized by using standard Boolian logic design. Referring specifically to FIG. 5d, the flow chart depicts in detail the programming of the state timing and control circuits 421.

Opto-isolation circuit 539 isolates the A/D digital output to prevent digital noise feedback from the digital signal processor signal bus 435.

Referring to FIG. 5e, the RF transmitter control circuit 405 is digital. The digital signal processor 425 in conjunction with transmitter pulse counter 541 sets the number of cycles of the transmit clock 419 that are used to create the burst. The number of transmit clock cycles determines the bandwidth of the RF burst, and the sample resolution of the depth gate. By dynamically setting the number of cycles in the RF transmit burst, the digital signal processor 425 can employ the Doppler received signal-to-noise as a feedback input to adjust the transmitter signal for the specific blood vessel being examined.

In addition to the number of cycles used in the transmit burst, the power level of the transmit voltage is also adjustable. The digital signal processor 425 sets the DC voltage applied to the RF transmitter control circuits 405 power driver output by adjusting programmable attenuator 543 and power source 545 from a minimum power level of approximately 60 VDC. Again, the digital signal processor 425 evaluation of signal-to-noise in the received signal determines the power level chosen for the vessel examined.

Note that the transmitter signal of the RF transmitter control circuit 405 that is used to excite the transducer ceramic element is flexible. The signal is modifiable under software control of the digital signal processor 425. Thus, both simple transducer excitation and complex excitation are achievable. The specific excitation signal transmitted can be dynamically determined, as necessary, to optimize the overall instrument's sensitivity to penile blood flow.

Wave Form Collecting and Processing Apparatus Operation

Referring now to FIGS. 6-10, the wave form collecting and processing apparatus of the present invention employs the below detailed software program to process blood flow wave form data.

In the preferred embodiment, the software programming of the ditigal signal processor 425 and the host computer 449 is comprised of a host computer examination program (FIG. 6), host computer examination loop subroutine (FIG. 7), event recording loop subroutine (FIG. 8), digital signal processor Doppler flow examination program (FIG. 9), and Doppler data processing subroutine (FIG. 10).

FIG. 6 is a flow diagram of the host computer (449) examination program. At block 601, the host computer 449 initializes peripheral archive devices, tests the user interface, and tests for the on-line presence of digital signal processor (slave) 425. At block 603, the digital signal processor's software is downloaded for real time

patient examination, and the host computer 449 checks for a ready signal from digital signal processor 425 before continuing.

Block 605 is a decision block that inquires whether the subject is ready for examination. If the patient is ready, at block 607 the examination clock is set to run for a predetermined time period.

Data from ditigal signal processor (slave) 425 is processed at block 609, the host computer examination loop, discussed further in conjunction with FIG. 7. Block 611 is a decision block that inquires whether the examination is completed. If the examination is not completed, block 609 is repeated. If the examination is completed, the data from the digital signal processor 425 is, at block 613, analyzed and compared to reference penile blood flow wave forms stored in memory in host computer 449.

At block 615, data is saved in a permanent file in archive device 457. At block 617, a patient report print-out is generated by printer 459. Block 619 ends the examination.

FIG. 7 is a flow diagram of the host examination loop subroutine 609. At block 701, host computer 449 waits for Doppler penile blood flow wave form data from the digital signal processor (slave) 425. At block 703, the digital signal processor data, raw transducer data, active transducer number and the time of the data run are all saved in the archive device 457.

Block 705 is a decision block that inquires whether penile blood flow wave form processed by digital signal processor 425 is equal to erectile phase 0. If the data is equal to phase 0, at block 707, the data is saved in a buffer of size 3. If the buffer already contains three phase 0 data events, the oldest one is dumped. Block 707 leads to block 701, above.

If, however, at decision block 705, the penile blood flow wave form processed by the digital signal processor 425 does not equal erectile phase 0, decision block 709 will then inquire whether the buffer has three events. If the buffer does not have three events, all phase 0 data is flushed from the buffer at block 715 and the program goes to block 701. If the buffer has three events, the three phase 0 events are saved and the non-phase 0 event is also saved. The program then proceeds to event recording loop subroutine 713 discussed further in conjunction with FIG. 8. From event recording loop subroutine 713, and program goes to block 701 via block 715, discussed above.

FIG. 8 is a flow diagram of the event recording loop subroutine 713. At block 801, host computer 449 waits for the digital signal processor 425 to process the penile blood flow profile for the active transducer 101, 103, 105 or 107. At block 803, archive data is saved in the archive device 457 and data is saved to the patient data file for event processing and final examination report.

Block 805 is a decision block that inquires whether the digital signal processor calculated event was a phase 0

event. If the event was not a phase 0 event, at block 809 the phase 0 event counter is cleared, and the program goes to block 801, above.

However, if the event was a phase 0 event, at block 807 'one' is added to the phase 0 event counter, and the program goes to decision block 811.

Decision block 811 inquires whether the phase 0 event is the third phase 0 event in succession. If the event is the third phase 0 event in succession, the event recording subroutine loop ends at block 813.

If the event is not the third phase 0 event in succession, the program goes to block 801, above.

FIG. 9 is a flow diagram of the digital signal processor Doppler flow examination program. Block 901 tests the host computer's input/output devices and tests the noise level of each Doppler transducer 101, 103, 105 and 107. A ready to process message is sent to host computer 449 at block 903.

Block 905 is a decision block that inquires whether to begin, based on host computer command. If the program is not to begin, the program goes to block 903, above. If the program is to begin, the program goes to block 907 where the transducer 101, 103, 105 or 107 is selected, the transducer power is adjusted, the depth of maximum blood flow is ascertained, cosine 0 is calculated, and the low pass filter is adjusted for best signal-to-noise.

At block 909, the Doppler data processing subroutine discussed further in conjunction with FIG. 10, a three minute, for example, spectrogram of Doppler blood flow is

preferred. Block 911 sends the examination results to host computer 449.

Block 913 is a decision block that inquires whether the examination is over. If the examination is not over, the program proceeds to block 907, above. If the examination is over, the program proceeds to block 915, which shuts off transducers 101, 103, 105 and 107 and ends the digital signal processor DSP Doppler flow examination program.

FIG. 10 is a flow diagram of the Doppler data processing subroutine 909. Block 1001 performs Fast Fourier transform/spectrogram on the Doppler time series data. Block 1003 reads the data from the optional systemic blood flow transducer. At block 1005, the erectile phase 0, 1A, 1B, 2, 3, 4, 5A or 5B is ascertained based on blood flow wave form parameters.

All raw data is saved for host computer archive device 457 at block 1007. Also at block 1007, all calculated Doppler flow parameters are saved for host computer archive device 457. Again, at block 1007, the erectile phase determination is saved for host computer archieve device 457.

Block 1009 exits the process Doppler data subroutine. Note that the data saved in the present subroutine is passed to host computer 449, and the memory reserved for this subroutine's data collection is reused for the next data event.

Penile Blood Flow Wave Form Data

Referring now to FIGS. 11 through 21, penile blood flow wave forms for normal and erectile dysfunctional males are shown. The above wave forms are exemplary of reference penile blood flow wave forms stored in memory of the host computer 449 of the present invention for comparison with the subject's penile blood flow wave forms, as discussed above. Also, the above wave forms are exemplary of the subject's penile blood flow wave forms sensed by penile transducers 101, 103, 105 and 107 that are subsequently compared to the reference penile blood flow wave forms by the present invention, as discussed above.

The penile blood flow wave forms of FIGS. 11 through 21 were based on empirical data collection under the following operating conditions. Doppler sensors having the above described operational parameters of penile transducers 101, 103, 105 and 107 in their Doppler measurement embodiment were manually placed adjacent to the subject's penis for penile blood flow data collection. It is readily apparent, however, that pulse oximetry transducers could also be employed.

In order to induce erection, intracorporal injection of papaverine (30 mg) (Eli Lilly, Indianapolis, IN) and "REGITINE" (1 mg) (phentolamine mesylate; Ciba-Geigy, Summit, NJ) were employed. However, the use of papaverine and "REGITINE" was to induce erection in an inhibiting clinical environment. The present invention contemplates data collection both without erection inducing pharmaceuticals by

normal nocturnal penile tumescence, and with these pharmaceuticals.

Two 21-gauge needles were placed into the midshaft of the left corpus cavernosum. One needle was used for the above pharmaceutical delivery, the other for continuous pressure monitoring with an Abbott Critical Care Systems Transpac III strain-gauge transducer (Abbott Laboratories; Abbott Park, IL) connected to a Spacelabs 512D monitor with oval pressure channels (Spacelabs; Seattle, WA). Use of the above invasive strain-gauge pressure transducer was for acquisition of intracorporal pressure reference data described further below. The present invention contemplates extrapolation of the subject's actual intracorporal penile pressure based on this intracoporal reference data, thus alleviating the need for invasive needle-based measurements.

Referring to FIGS. 11 through 18, the penile erection phases 0, 1A, 1B, 2, 3, 4, 5A and 5B are shown as a function of penile Doppler blood flow (velocity (cm per sec) vs time) in normal males. Specifically, FIGS. 11 through 21 show arterial blood flow into the two corpus cavernosa 201 by cavernosal arteries 203. While cavernosal arterial blood flow is analyzed in FIGS. 11 through 21, it is readily apparent that the present invention can also measure and process penile blood flow wave forms based on venous blood flow and bulbo-urethral 213 or dorsal arterial 207 blood flow.

In phase 0 of FIG. 11 (showing normal penile function), the penis is flaccid and blood flow is negligible.

In phase 1A of FIG. 12 (showing normal penile function), the corpus cavernosum is contracted (low volume) and inelastic. This is because of increased tone in the perisinusoidal smooth muscles. Although pretumescent intracorporal pressure is low, resistance to arterial inflow is high. In the flaccid penis, penile blood flow appears to be shunted away from the corpora cavernosa and toward the glans, skin, and urethra. Phase 1A denotes the transition between undetectable and continuous blood flow. Blood flow progresses from zero flow or intermittent flow to pulsatic flow, with increasing systolic and diastolic velocities. At the beginning of this phase, the initiation of systolic flow is gradual. By the end of the phase, the initiation of systolic flow is rapid. The total flow measured by integration of the wave form increases during this phase from near zero to near maximum. The flow pattern of this phase is commonly detected in both functional and dysfunctional males (see FIGS. 12 and 19-21).

During tumescence, in phase 1B of FIG. 13 (showing normal penile function), cavernosal artery flow wave forms and velocities are influenced by both cavernosal artery vasodilatation and changing intracorporal pressure. Cavernosal artery flow evolves in response to these dynamic events. Early in tumescence, the cavernosal artery dilates and the intracorporal resistance is minimal. Continuous flow through the entire cardiac cycle is the key characteristic of this phase 1B. Systolic flow is maximum or near maximum. Diastolic flow is maximum. The onset of the systolic inflow

is rapid, and the total flow, by wave form integration, is near maximum. This blood flow pattern is detected in all functional males and in dysfunctional males who progress past phase 1A (see FIGS. 13 and 19-21).

Phase 2 of FIG. 14 (showing normal penile function), occurs as the sinusoids fill and the venous sinusoidal occlusion mechanism closes. Blood then becomes trapped within the corpora cavernosa. Intracorporal pressure and resistance increase. In response, diastolic inflow decreases. The onset of increased intracorporal resistance is heralded by the dicrotic notch and a decrease in end-diastolic velocity. The diastolic velocity continues to diminish as intracorporal pressure increases. This decrease in diastolic velocity and increase in intracorporal pressure is characteristic of this phase 2. Systolic flow is near maximum and its onset is rapid. The length of the systolic flow cycle begins to shorten. The total flow, as measured by integration, decreases with the decreasing diastolic flow (due to increased intracorporal pressure). While functional males progress to phase 2, males with severe venous sinusoidal leaks (such that intracorporal pressure is low) most often do not progress past this phase. However, males with venous abnormalities that allow higher intracorporal pressure, as well as males with arterial abnormalities, progress past this phase (see FIGS. 14 and 19-21).

In phase 3 of FIG. 15 (showing normal penile function), intracorporal pressure is equal to peak diastolic pressure and the diastolic signal will approximate zero. Blood cannot

be pumped into the corpora cavernosa during diastole when the intracorporal pressure exceeds the peak diastolic pressure in the cavernosal artery. As a consequence, inflow is restricted to systole. Systolic velocity is near maximal. The length of the systolic cycle continues to shorten. The total flow continues to diminish. Males with minimal sinusoidal leakage and/or minimal arterial insufficiency as well as normal males progress to phase 3 (see FIGS. 15 and 19-21).

Phase 4 of FIG. 16 (showing normal penile function), is defined by reverse diastolic flow. When intracorporal pressure exceeds the peak diastolic pressure of terminal branches of the cavernosal artery (hilicine arteries), diastolic flow reversal is observed in the main cavernosal artery. Diastolic flow reversal becomes more prominent as intracorporal pressure increases until the entire diastolic cycle is involved. As intracorporal pressure continues to increase, the intracorporal portion of the cavernosal artery becomes narrowed (but not occluded) as the walls of the cavernosal artery are compressed by their surrounding sinusoids. Systolic velocities increase to near maximal. The combination of intracorporal cavernosal artery narrowing and extracorporal cavernosal artery vasodilatation produce the increase in systolic velocities during phase 4. Total flow continues to decrease. While normal males progress to phase 4, very few, if any, dysfunctional males do so (see FIGS. 16 and 19-21).

Phase 5 of FIGS. 17 and 18 (showing normal penile function), is characterized by the eventual loss of both systolic and diastolic flow signals. The first half of this phase, 5A (FIG. 17), is defined by the loss of both forward systolic and reversed diastolic flow components. Loss of flow reversal occurs during end diastole, while velocity and the duration of the systolic component decreased continuously. Phase 5B (FIG. 18), the second half of phase 5, is the end stage of the flow cycle and is defined by loss of both systolic and diastolic flow. All flow ceases when intracorporal pressure equals or exceeds peak systolic velocity. Phase 5 only occurs in normal males, but not all normal males consistently progress to phase 5 (see FIGS. 17, 18 and 19-21).

Referring now to Table 1 below, mean systolic occlusion pressure (mean SYSTOP) maximal systolic velocity and maximal diastolic velocity are shown as a function of systolic occlusion pressure (SYSTOP).

Table 1

SYSTOP (mmHg)

	<50	50-80	>80
Mean SYSTOP (mmHg)	34	71	105
Max. Systolic Vel. (cm/sec)	10	26.9	38.1
Max. Diastolic Vel. (cm/sec)	4.4	9.5	13.2

SYSTOP denotes the cessation of cavernosal flow during erection. The above tabulated SYSTOP and mean SYSTOP pressures may be measured through the above described use of an invasive needle-based pressure transducer, and the infusion of saline through another needle inserted in the

subject's penis (note that an individual may also evidence SYSTOP naturally during full erection).

Table 1 shows a correlation between SYSTOP and both maximal systolic velocity and maximal diastolic velocity. This correlation supports the use of maximal systolic velocity and maximal diastolic velocity to predict arterial integrity (higher velocity and higher SYSTOP pressure denoting greater integrity). Thus it is readily apparent that the present invention can predict arterial integrity based on storage of the above SYSTOP pressure, maximal systolic velocity and maximal diastolic velocity of Table 2 in memory for processing by digital signal processor 425 and by host computer 449 with subject wave form data received by penile transducers 101, 103, 105 and 107. It is also readily apparent that the maximal systolic velocity and maximal diastolic velocity empirical data can also be obtained from reference penile wave forms as shown in FIGS. 11-18, and that the subject's arterial integrity can be directly ascertained from these values in conjunction with the subject's sensed wave forms by the processing of digital signal processor 425 and host computer 449.

Referring now to Table 2, below, mean intracorporal pressure, mean peak systolic velocity, time of systolic cycle and mean peak diastolic velocity are shown as a function of penile erection phases in normal males, as shown in FIGS. 11 through 18.

Table 2

Measurement	0	1A	1B	2	3	4	5A	5B
Mean pressure in mm Hg	10	11-17	17-25	25-40	40-63	63-83	83-105	106
Mean peak systolic vel. in cm/sec	12.5	---		32.0	22.0	29.5	39.0	<39.0	0
Time for sys. cycle in sec	---	---		0.285	0.27	0.22	0.17	<0.1	0
Mean peak diastolic vel. in cm/sec	0	---	10.0	<10.0		0	-6.4	-6.4-0	0

A key aspect of the present invention is the above correlation between mean intracorporal pressure and both penile erection phase and penile blood flow wave form. Storage of the above intracorporal pressure empirical data in memory for processing by digital signal processor 425 and by host computer 449 with wave form data received by penile transducers 101, 103, 105 and 107 from the subject allows the practitioner to ascertain intracorporal pressure without the needle-based pressure transducers inserted in the subject penis. Furthermore, the digital signal processor 425 and host computer 449 can readily derive intracorporal resistance (intracorporal pressure (mmHg)/flow velocity ml per min)) once intracorporal pressure and flow velocity are obtained.

Dividing penile erection phase performance based on specific physical dysfunction, the following is observed based on FIGS. 19-21, showing abnormal wave form data.

Referring to FIG. 19, males with bilateral severely abnormal cavernosal arteries and normal venous sinusoidal occlusion mechanisms demonstrate decreased peak systolic velocities and an erection pattern to phase 1 or 2. Males with intermediate cavernosal arteries and normal venous

sinusoidal occlusion mechanisms have a lower than normal systolic velocity but may demonstrate all phases 1-5, but with a temporal sequence progression that is longer than that of normal males.

In general males with abnormal arteries have lower systolic and diastolic flow velocities, and lower total flow. Also, the wave form will generally not progress to reversed diastolic flow.

Referring to FIG. 20, males with normal cavernosal arteries but severely defective sinusoidal occlusion mechanisms demonstrated peak systolic and diastolic velocities within normal range, but erection progression to only phase 1 or 2 based on the amount of intracorporal pressure present. If progression is to phase 2, no reverse diastolic flow is usually observed.

Referring to FIG. 21, males with both abnormal cavernosal arteries and venous sinusoidal occlusion mechanism have low systolic and diastolic velocities, and diminished final intracorporal pressure. These males do not progress to the later erection phases, and the progression through these phases occurs more slowly than normal. The wave form will resemble the wave form of either the arterial or venous dysfunctional male, depending on which of the arterial and venous dysfunction predominates.

All of the above correlations between penile erection phase and systolic velocity, diastolic velocity, and intracorporal pressure are readily apparent from the wave

form data for abnormal males of FIGS. 19 through 21 compared to the wave form data of normal males of FIGS. 11-18.

While particular embodiments of the present invention have been described in some detail herein above, changes and modifications may be made in the illustrated embodiments without departing from the spirit of the invention.

I claim:

1. An apparatus for sensing penile erectile function comprising:

a noninvasive sensor means adapted to be attached to a penis for producing electrical sensor signals representing penile blood flow wave forms; and

means for processing said electrical signals to produce a signal representing penile erectile function as a responsive function of said electrical analog sensor signals.

2. The apparatus of claim 1, wherein said signal representing penile erectile function is a signal representing penile erection phase.

3. The apparatus of claim 1, wherein said electrical sensor signals representing penile blood flow wave forms include electrical signals representing at least one of penile blood flow systolic velocity and penile blood flow diastolic velocity.

4. The apparatus of claim 1, wherein said signal representing penile erectile function includes a signal representing penile intracorporal pressure.

5. The apparatus of claim 1, wherein said signal representing penile erectile function includes a signal representing penile intracorporal resistance.

6. The apparatus of claim 1 wherein said electrical sensor signals representing penile blood flow wave forms include electrical analog signals representing penile blood oxygenation.

7. The apparatus of claim 1, wherein said means for processing said electrical sensor signals further comprises means for comparing said electrical sensor signal representing penile blood flow wave forms with preselected penile wave form data to derive said signal representing penile erectile function.

8. The apparatus of claim 7, wherein said preselected penile wave form data is representative of at least one of normal penile blood flow and abnormal penile blood flow.

9. The apparatus of claim 1, further comprising:

a noninvasive sensor means adapted to be attached to the patient for producing electrical sensor signals representing systemic arterial blood flow, and said means for processing said electrical sensor signals further comprises means for comparing said electrical sensor signals representing penile blood flow wave forms with said electrical signals representing systemic arterial blood flow to derive said signal representing penile erectile function.

10. The apparatus of claim 1, wherein said noninvasive sensor means includes a sensor for measuring penile arterial pulse wave Doppler shifts, said sensor comprising:

sound wave generating means;

sound wave receiving means;

attachment means for radial placement of said sound wave generating means and said sound wave receiving means around the penis and in proximity to a penile artery; and

signal conditioning and processing means for deriving a frequency shift in a sound wave transmitted by said sound wave generating means and received by said sound wave receiving means, the frequency shift being based on the velocity of blood cells in the penile artery.

11. The apparatus of claim 1, wherein said noninvasive sensor means includes a sensor for measuring penile blood oxygenation, said sensor comprising:

light wave generating means;

light wave receiving means;

attachment means for radial placement of said light wave generating means and said light wave receiving means around the penis and in proximity to a penile artery; and

signal conditioning and processing means for deriving light absorption frequencies in light waves transmitted by said light wave generating means and received by said light wave receiving means, the light absorption frequencies being based on the amount of oxygen in the penile arterial blood.

12. The apparatus of claim 1, further comprising a signal display means for displaying graphic representations of said electrical sensor signals from said noninvasive sensor.

13. The apparatus of claim 1, further comprising a signal display means for graphic display of said signal representing penile erectile function.

14. The apparatus of claim 1, further comprising:

a permanent memory storage means; and

a temporary memory storage means, said temporary memory storage means storing for a predetermined time period a first set of said electrical sensor signals, said first set of signals being processed by said means for processing during storage in said temporary memory storage means, said first set of signals being transferred to said permanent memory storage means after processing by said means for processing, said temporary memory storage means then storing for a predetermined time period at least a second set of signals based on said electrical sensor signals.

15. The apparatus of claim 14 wherein said means for processing said electrical signals further comprises:

a slave computer having said temporary memory storage means; and

a master computer having said permanent memory storage means.

16. An apparatus for sensing penile erectile function comprising:

a noninvasive sensor means adapted to be attached to a penis for producing electrical analog sensor signals representing penile blood flow wave forms, said electrical analog sensor signals including at least one of penile systolic velocity, penile diastolic velocity and penile blood oxygenation signals;

an analog-digital converter means for converting said analog electrical signals into digital signals; and

a means for processing said digital signals to derive a signal representing penile erectile function by comparing said digital signals with preselected penile wave form data.

17. The apparatus of claim 16, further comprising a signal display means for displaying graphic representations of said electrical analog sensor signals from said noninvasive sensor and of said signal representing penile erectile function.

18. An apparatus for sensing penile erectile function comprising:

a noninvasive sensor means adapted to be attached to a penis for producing electrical analog sensor signals

representing penile arterial pulse wave Doppler shifts, said electrical analog sensor signals including at least one of penile blood flow systolic velocity and penile blood flow diastolic velocity signals;

an analog-digital converter for converting said electrical analog sensor signals into digital signals;

a permanent memory storage means;

a temporary memory storage means, said temporary memory storage means storing for a predetermined time period a first set of said digital signals and subsequently transferring said first set of said digital signals to said permanent memory storage means, said temporary memory storage means then storing for a predetermined time period at least a second set of said digital signals;

a means for processing said digital signals to derive a signal representing penile erectile function by comparing said digital signals in said temporary memory storage means with preselected penile wave form data, said signal representing penile erectile function including a signal representing at least one of penile intracorporal pressure and penile intracorporal resistance; and

a signal display means for displaying graphic representations of said electrical analog sensor signals from said noninvasive sensor and of said signal representing penile erectile function.

19. The apparatus of claim 18, further comprising:

a noninvasive sensor means adapted to be attached to a penis for producing electrical analog sensor signals representing penile blood oxygenation, said electrical analog sensor signals representing penile blood oxygenation being converted by said analog-digital converter, stored in said temporary memory storage means and then in said permanent memory storage means, and processed by said means for processing by comparison with preselected wave form data to derive a signal representing penile erectile function.

20. The apparatus of claim 18, further comprising:

a noninvasvie sensor means adapted to be attached to the patient for producing electrical analog sensor signals representing systemic arterial blood flow, said electrical analog sensor signals representing systemic arterial blood flow being converted by said analog-digital converter, stored in said temporary memory storage means and then in said permanent memory storage means, and processed by said means for processing by comparison with said digital signals based on said electrical analog sensor signals to derive a signal representing penile erectile function.

21. A method for sensing penile erectile function comprising the steps of:

receiving from a noninvasive sensor means attached to a penis electrical analog sensor signals representing penile blood flow wave forms;

converting in a means for analog to digital signal conversion said analog electrical signals into digital signals; and

processing in a computer means said digital signals by comparison of said digital signals to predetermined penile wave form data to derive a signal representing penile erectile function.

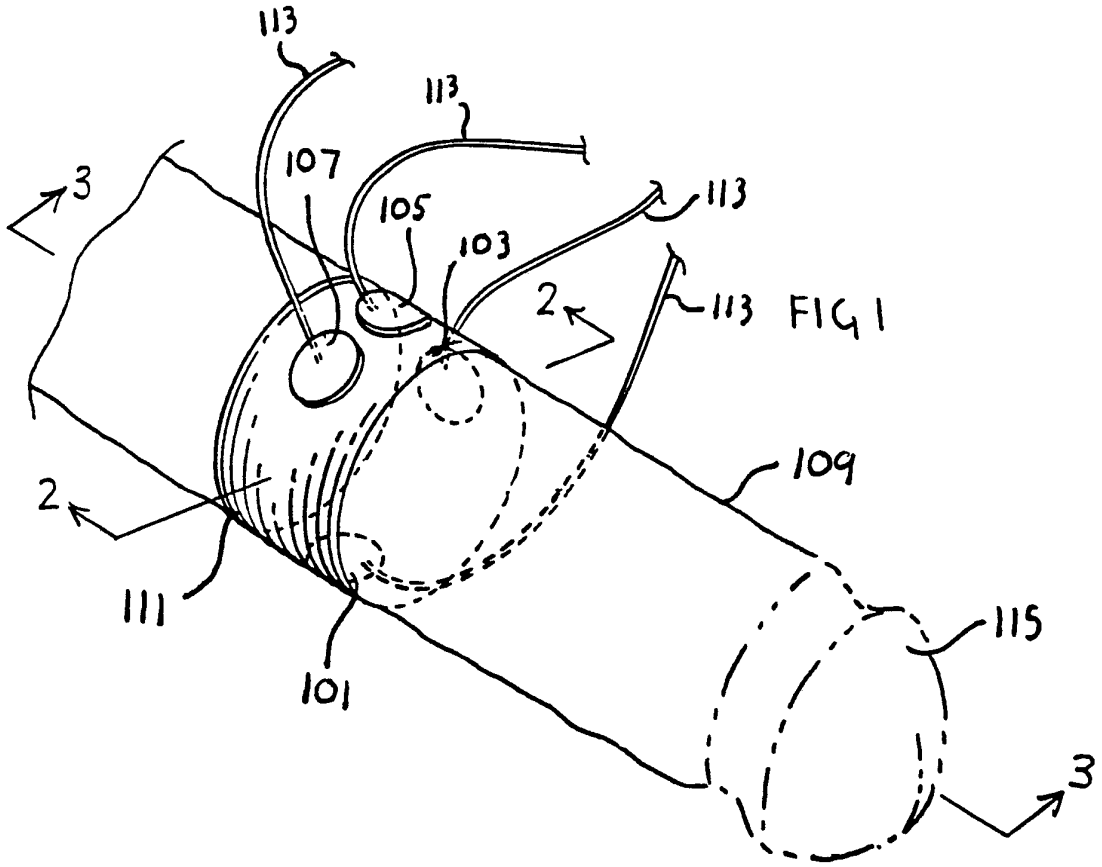
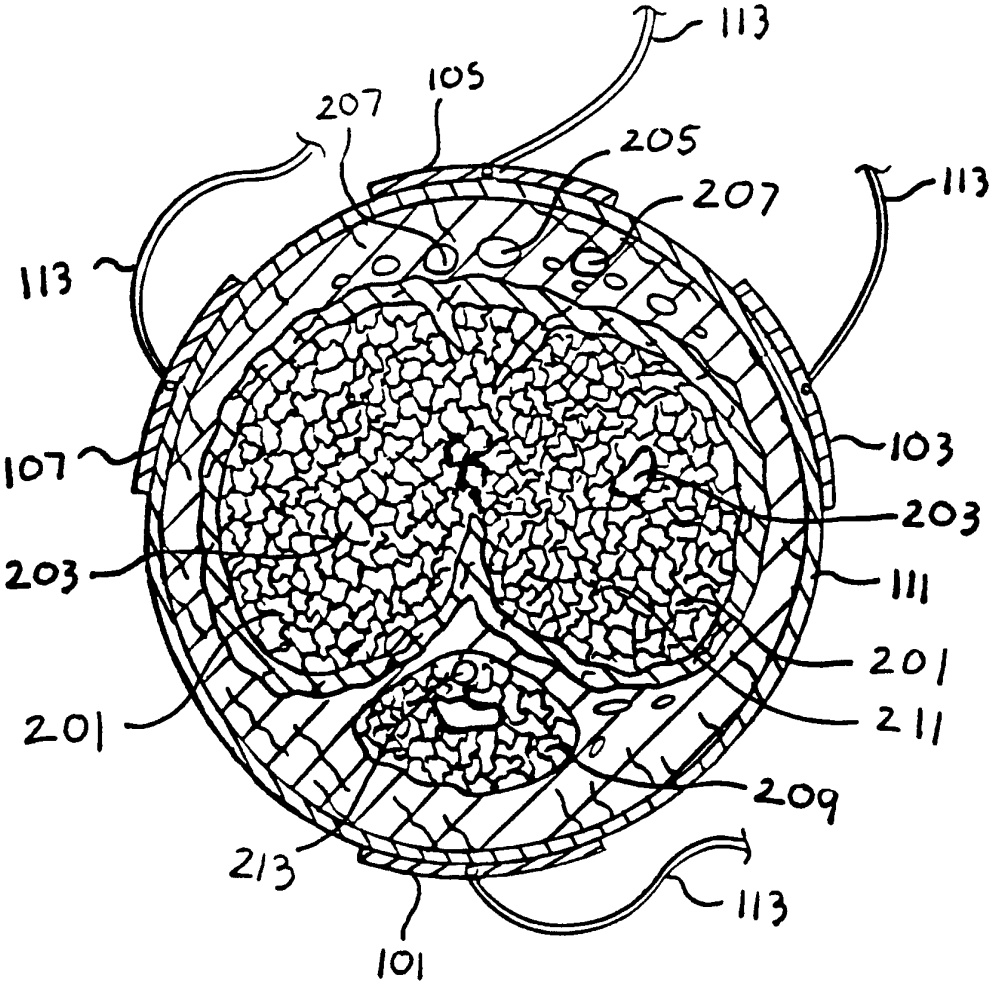


FIG 1

FIG 2


113
105
207
205
207
113
113
107
103
203
203
111
201
211
201
209
213
113
101

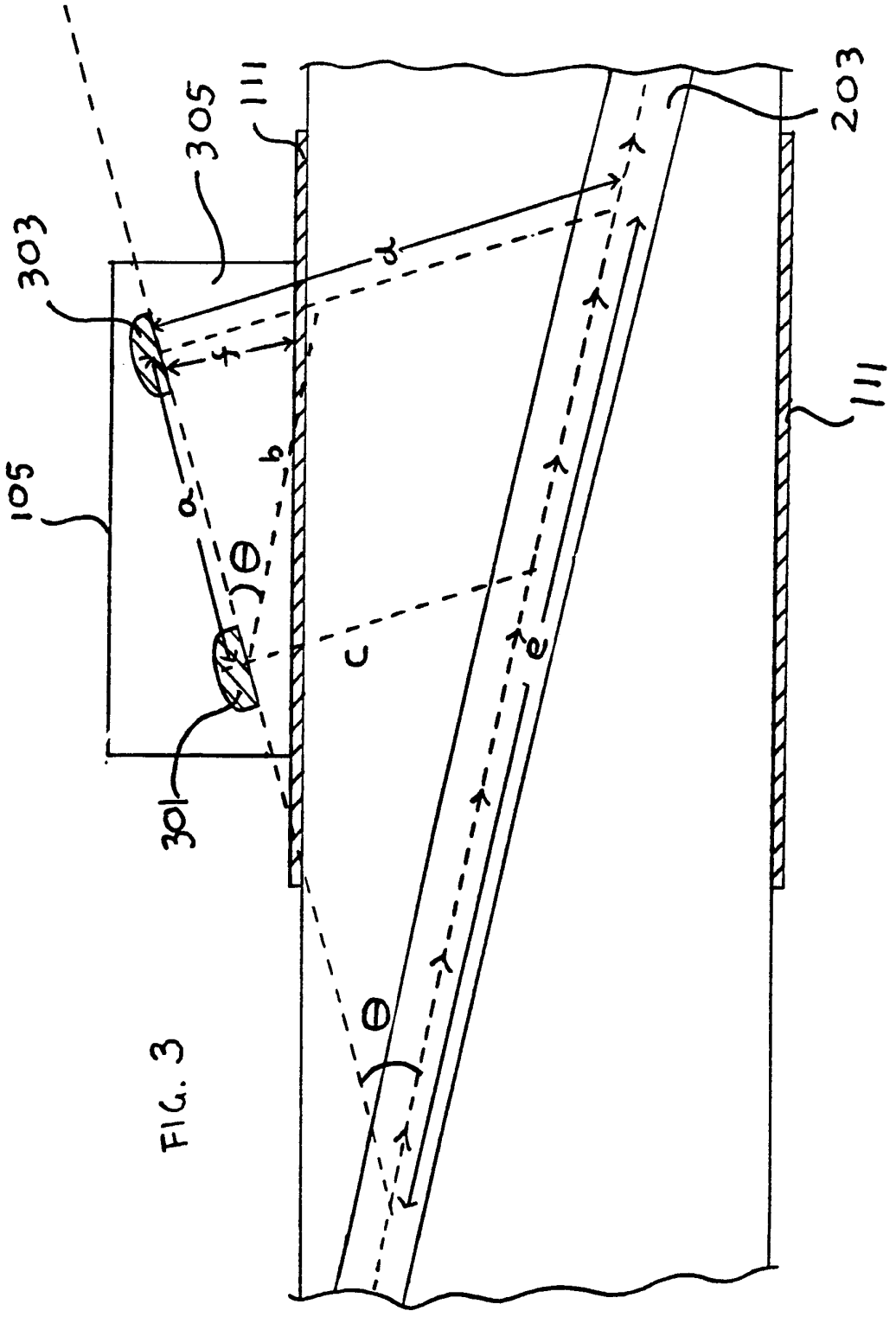


FIG. 3

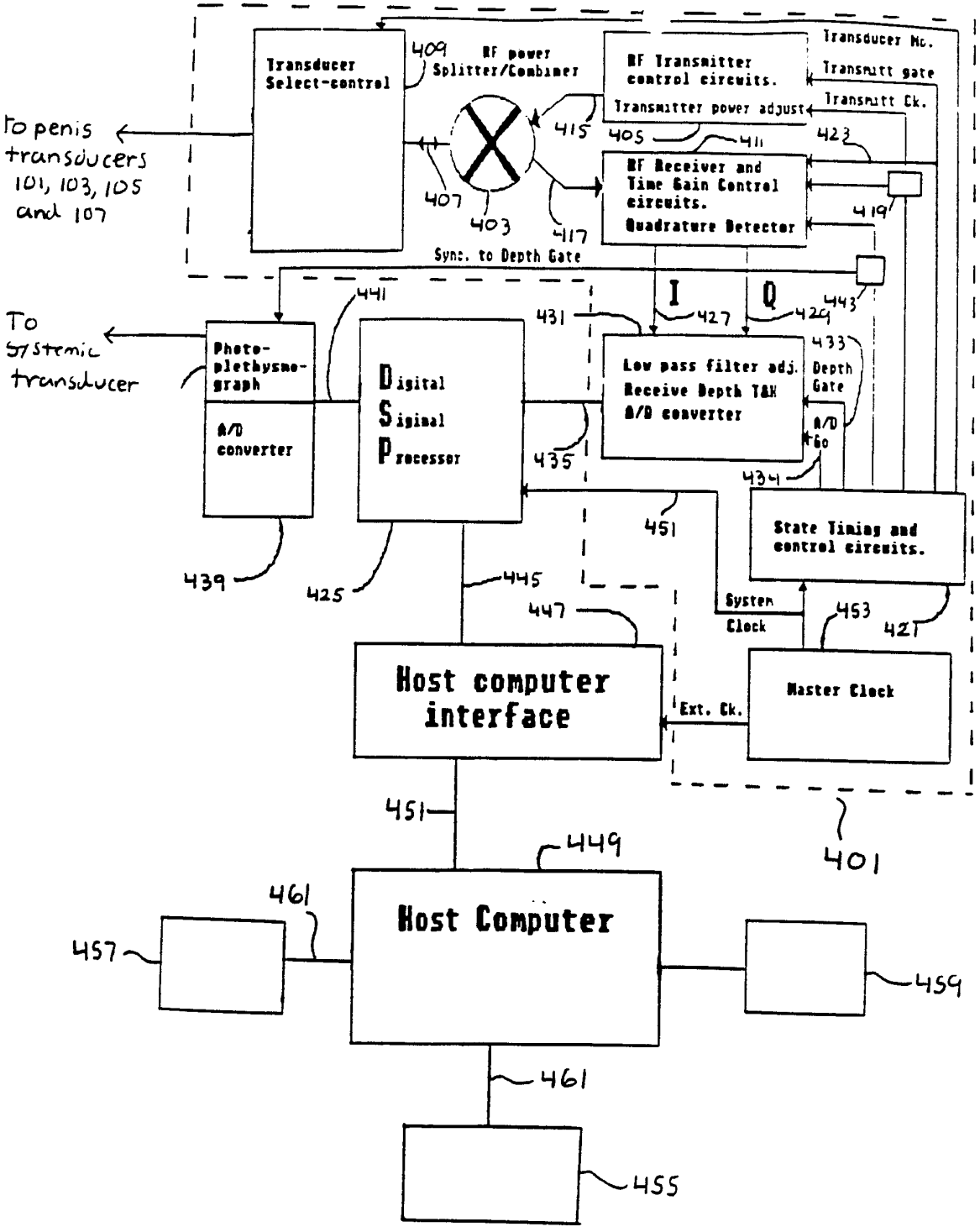

To penis transducers 101, 103, 105 and 107
Transducer Select-control
409
RF power Splitter/Combiner
RF Transmitter control circuits.
Transducer No.
Transmitt gate
Transmitt Clk.
Transmitter power adjust
405
411
415
423
RF Receiver and Time Gain Control circuits. Quadrature Detector
419
407
403
417
Sync. to Depth Gate
I
Q
443
To Systemic transducer
441
431
427
429
Photo-plethysmo-graph
A/D converter
Digital Signal Processor
Low pass filter adj. Receive Depth T&H A/D converter
433
Depth Gate
A/D Go
435
434
451
State Timing and control circuits.
439
425
445
447
System Clock
453
421
Host computer interface
Ext. Ck.
Master Clock
401
451
449
461
Host Computer
457
459
461
455

FIG 4

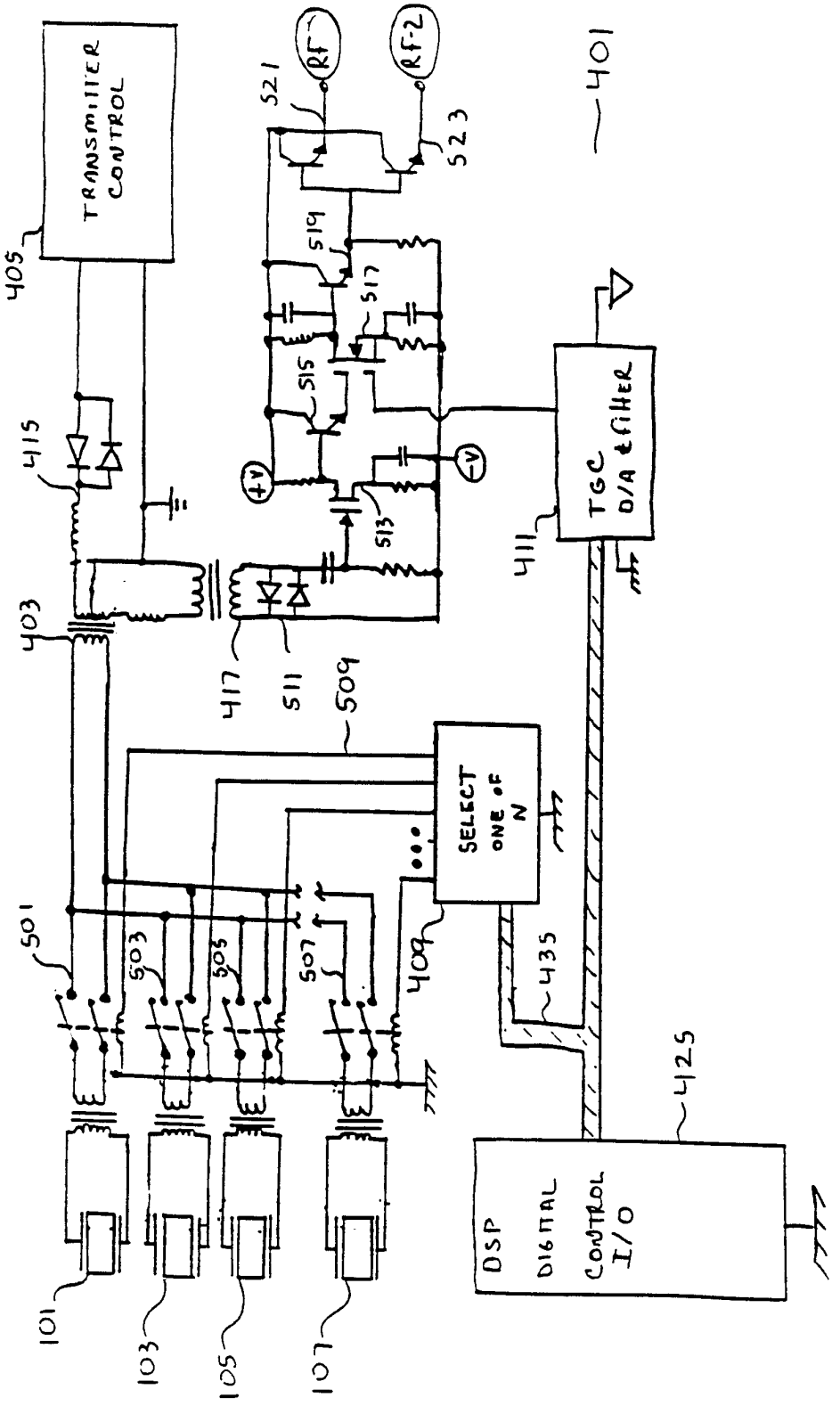

TRANSMITTER CONTROL
405
415
403
417
511
509
521
RF-1
RF-2
523
401
519
517
515
513
+V
-V
TGC D/A & FILTER
411
SELECT ONE OF N
409
501
503
505
507
435
425
DSP DIGITAL CONTROL I/O
101
103
105
107

FIG 5a

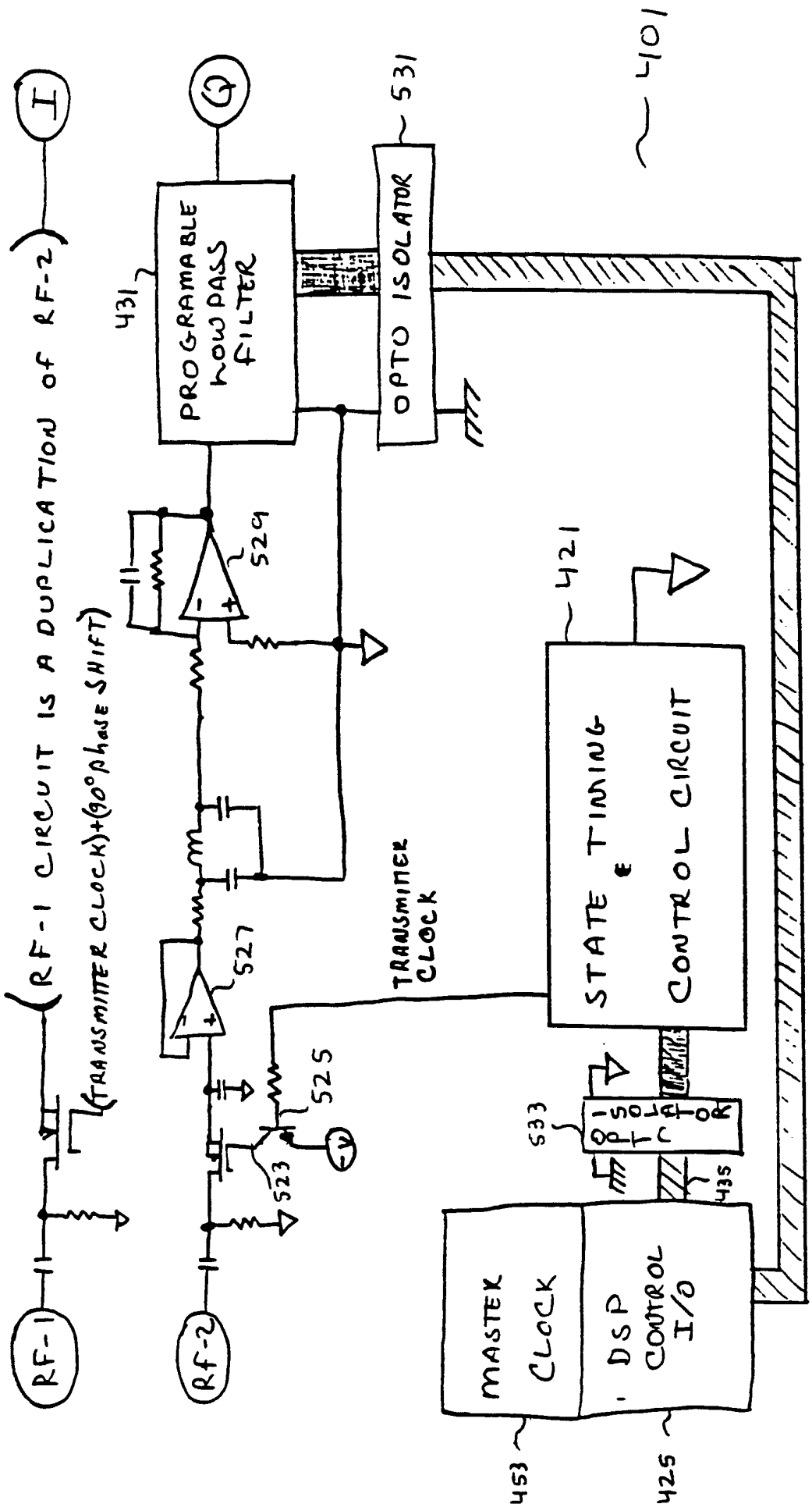

I
Q
RF-1 CIRCUIT IS A DUPLICATION OF RF-2
(TRANSMITTER CLOCK)+(90° PHASE SHIFT)
PROGRAMABLE LOW PASS FILTER
431
OPTO ISOLATOR
531
401
529
527
525
523
TRANSMITTER CLOCK
421
STATE TIMING & CONTROL CIRCUIT
533
POLAROID
435
RF-1
RF-2
MASTER CLOCK
DSP CONTROL I/O
453
425

FIG 5b

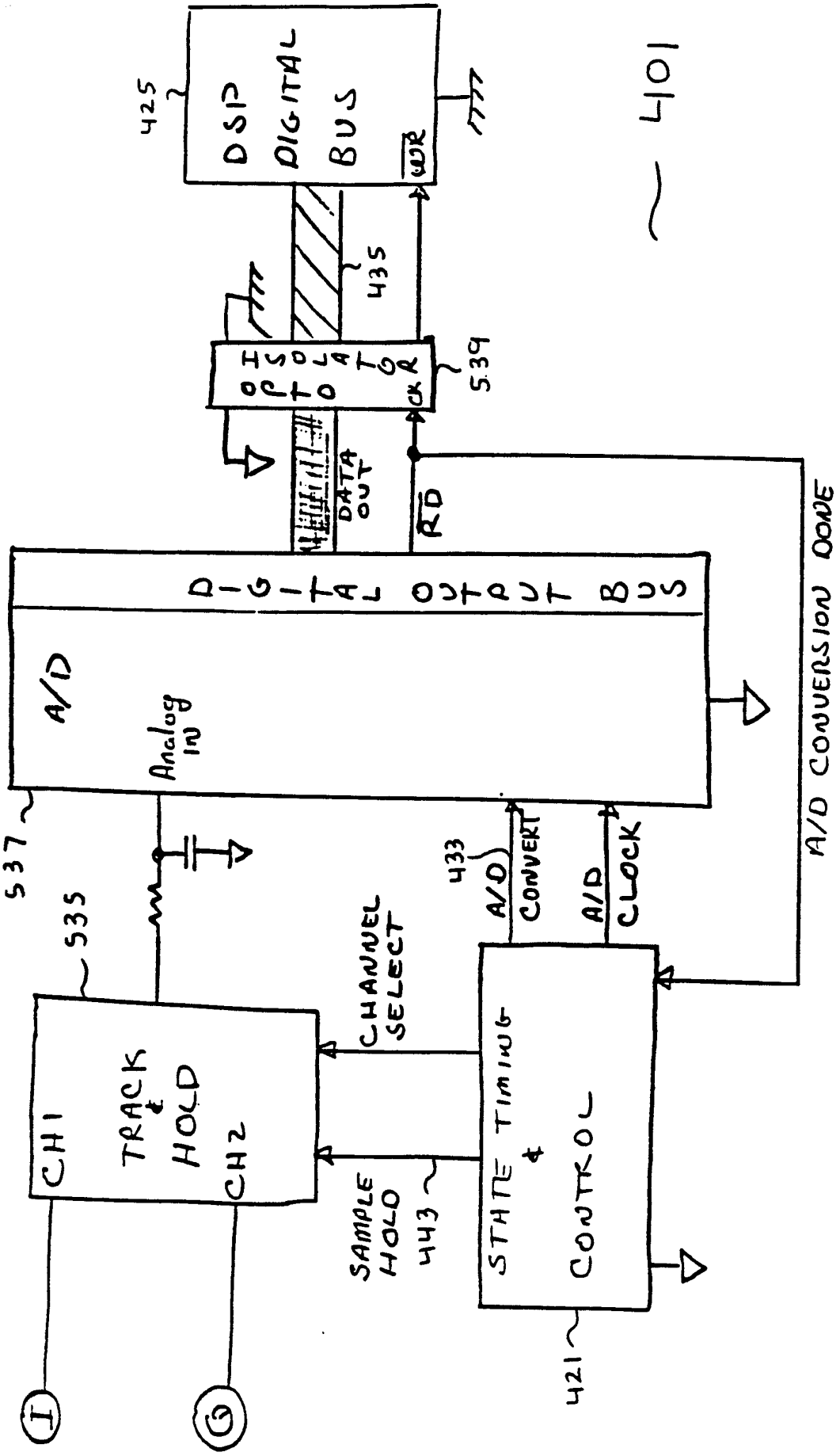

DSP DIGITAL BUS
425
WR
435
HOLD
539
DATA OUT
RD
DIGITAL OUTPUT BUS
A/D
Analog IN
537
535
CH1
TRACK & HOLD
CH2
CHANNEL SELECT
SAMPLE HOLD
443
433
A/D CONVERT
A/D CLOCK
STATE TIMING & CONTROL
421
A/D CONVERSION DONE
401
I
Q

FIG 5C

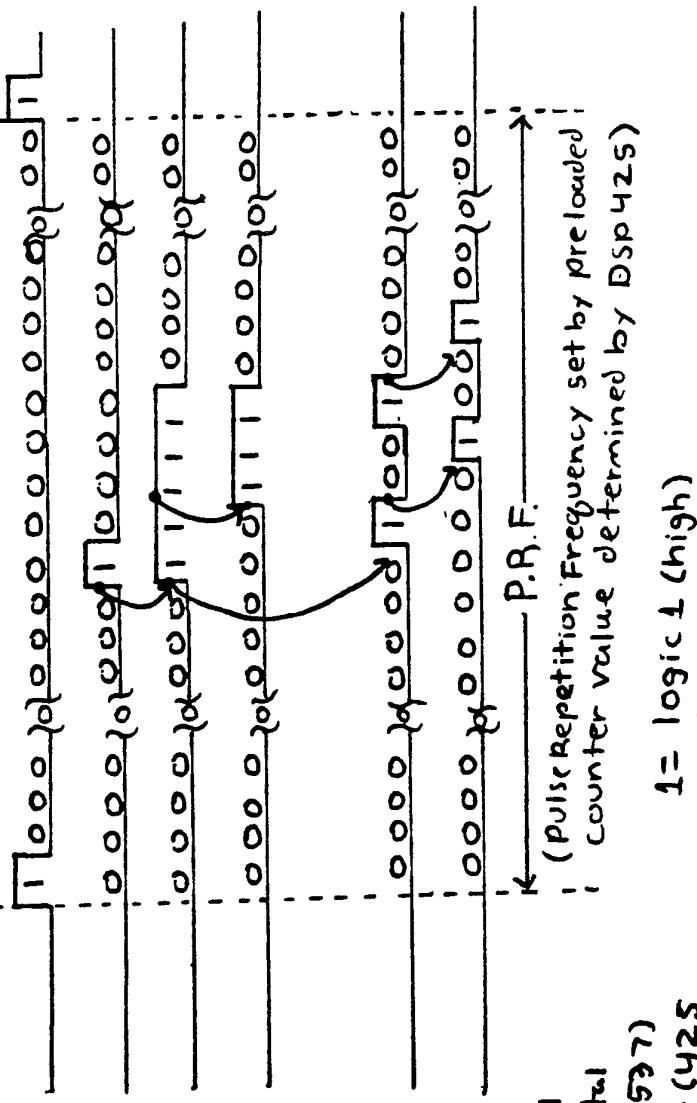

State Timing Sequence
0 1 2 3 4 . . . n . . . . N
Transmitter Gate (423)
Depth Gate (433) - occurs n timer clocks after transmitter gate (12 n ≤ (N-5))
Sample Hold (443)
Channel Select
0 for I (427)
1 for Q (429)
A/D Convert (434)
RD (A/D End of Convert) - where RD = READ, the final logic state to latch the digital output of A/D converter (537) into digital signal processor (425.
P.R.F.
(Pulse Repetition Frequency set by preloaded counter value determined by DSP 425)
1= logic 1 (high)
0 = logic 0 (low)

FIG 5d

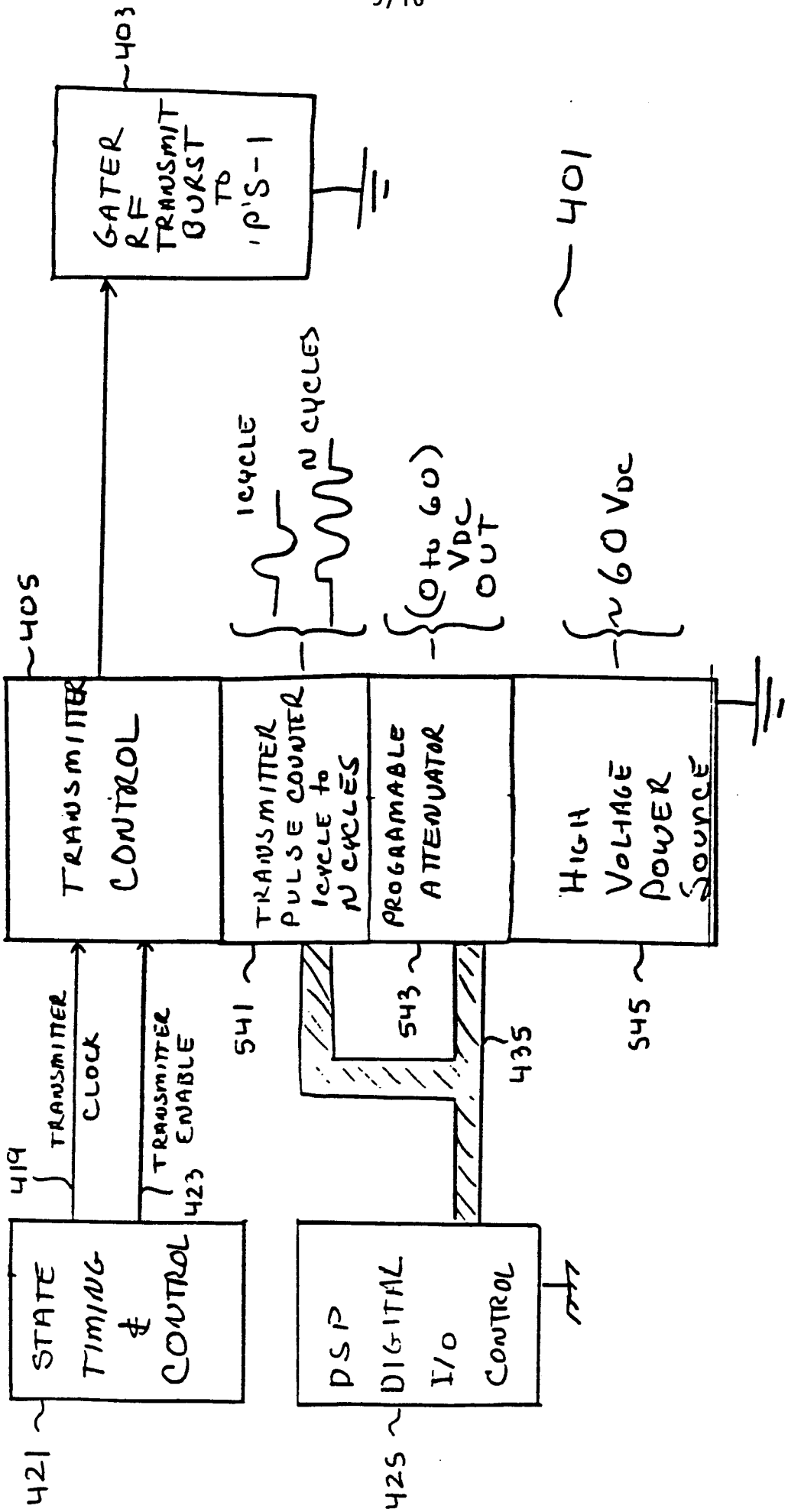

403
GATER RF TRANSMIT BURST TO IP'S-1
401
405
TRANSMITTER CONTROL
1 CYCLE
N CYCLES
(0 to 60) VDC OUT
~60 VDC
TRANSMITTER PULSE COUNTER 1 CYCLE to N CYCLES
PROGRAMABLE ATTENUATOR
HIGH VOLTAGE POWER SOURCE
541
543
545
435
419
TRANSMITTER CLOCK
423
TRANSMITTER ENABLE
STATE TIMING & CONTROL
421
DSP DIGITAL I/O CONTROL
425

FIG 5e

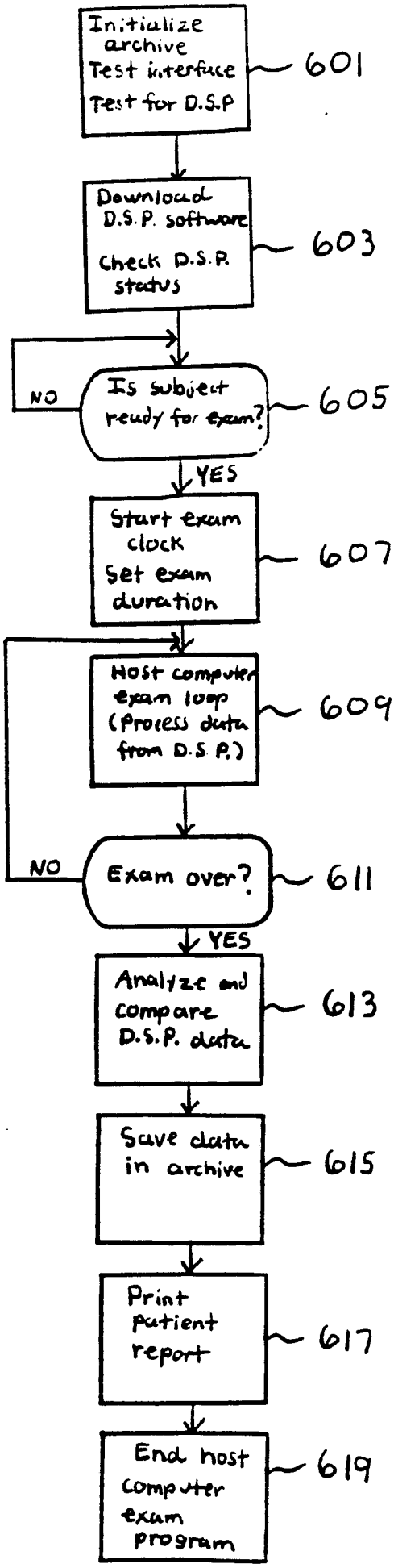

Initialize archive
Test interface
Test for D.S.P
601
Download D.S.P. software
Check D.S.P. status
603
NO
Is subject ready for exam?
605
YES
Start exam clock
Set exam duration
607
Host computer exam loop (Process data from D.S.P.)
609
NO
Exam over?
611
YES
Analyze and compare D.S.P. data
613
Save data in archive
615
Print patient report
617
End host computer exam program
619

FIG 6

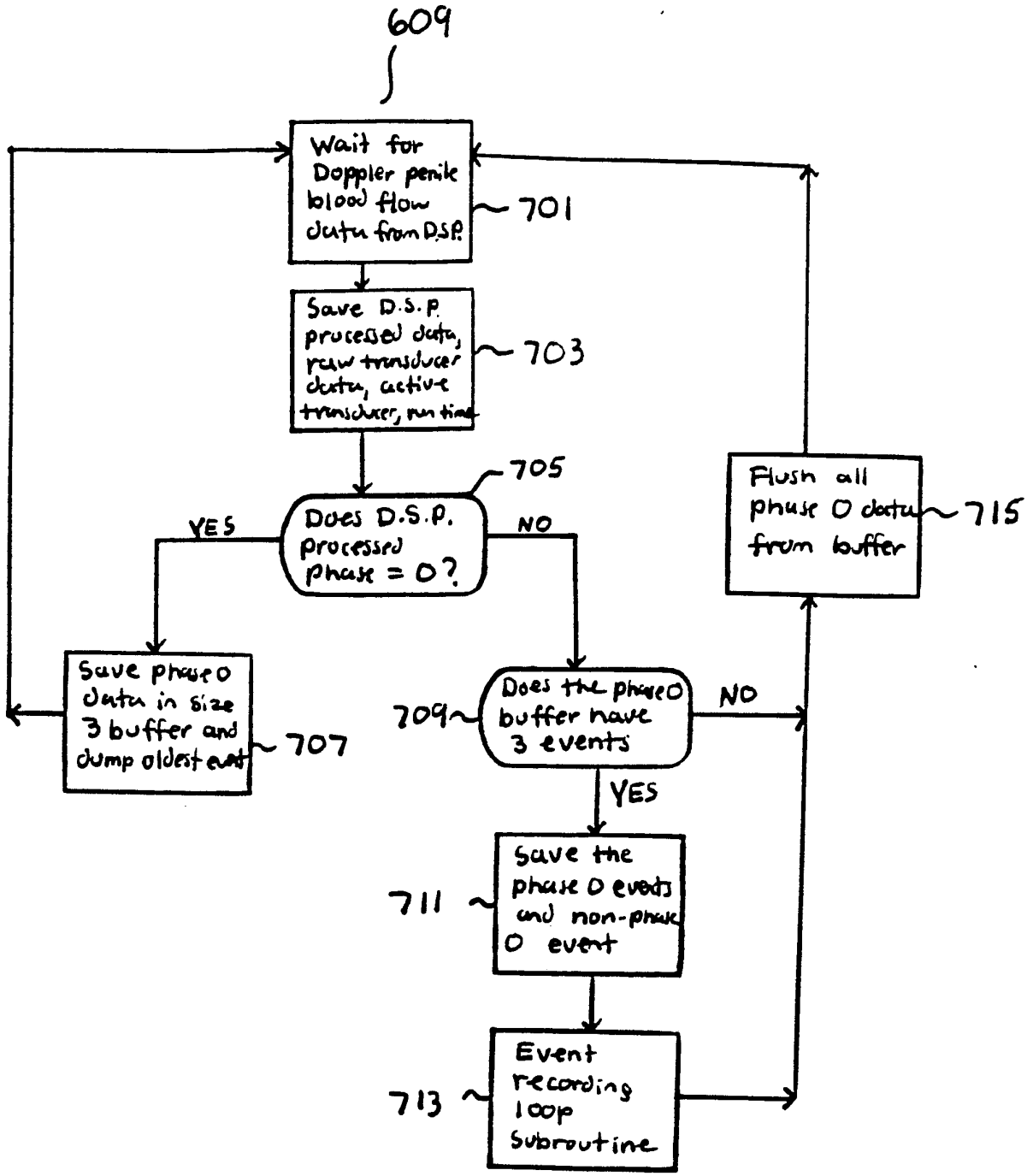

609
Wait for Doppler peak blood flow data from D.S.P.
701
Save D.S.P. processed data, raw transducer data, active transducer, run time
703
705
Does D.S.P. processed phase = 0?
YES
NO
Save phase 0 data in size 3 buffer and dump oldest event
707
709
Does the phase 0 buffer have 3 events
NO
YES
711
Save the phase 0 events and non-phase 0 event
713
Event recording loop subroutine
Flush all phase 0 data from buffer
715

FIG 7

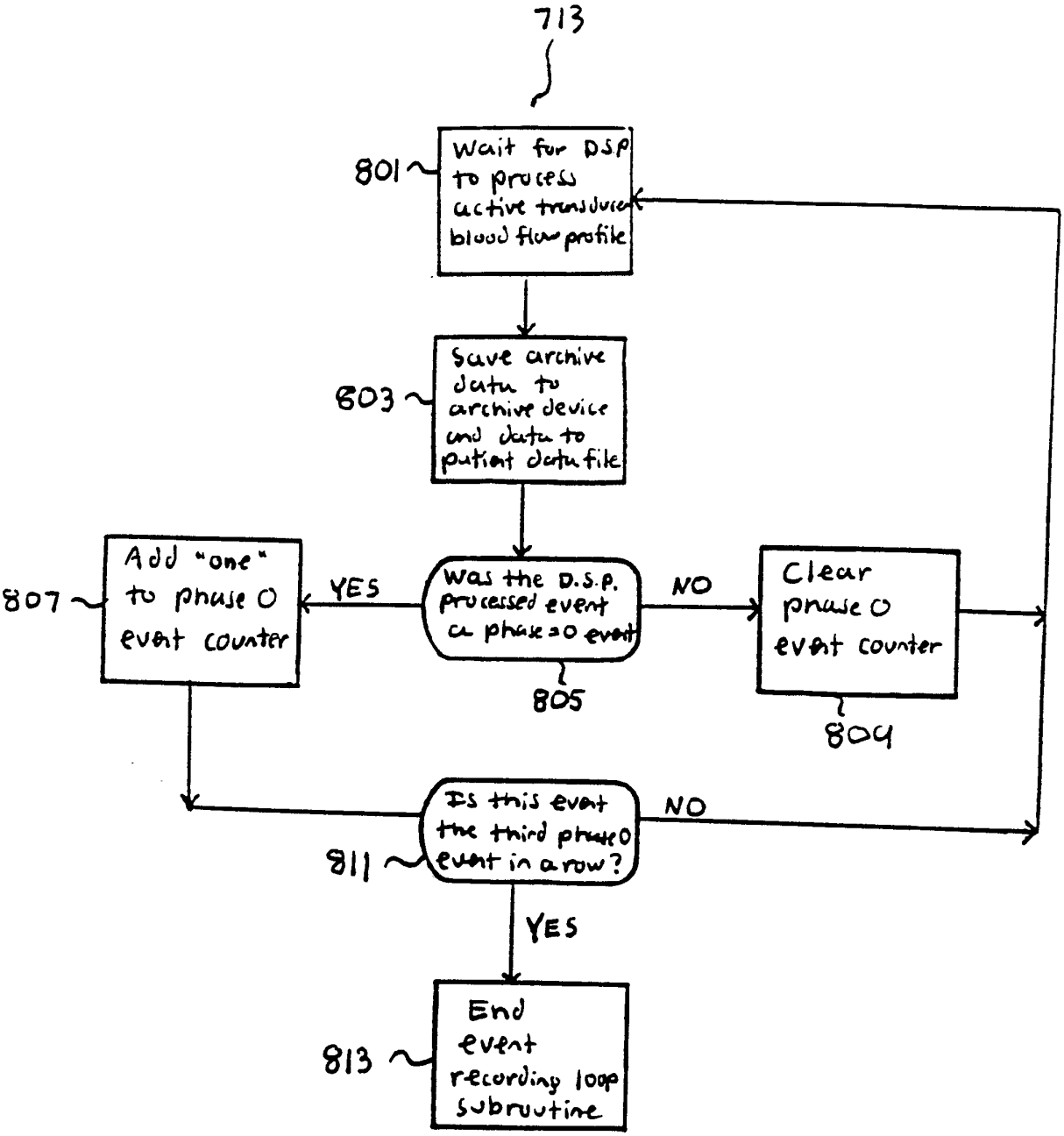

713
801
Wait for DSP to process active transducer blood flow profile
803
Save archive data to archive device and data to patient data file
Was the D.S.P. processed event a phase=0 event
805
YES
807
Add "one" to phase 0 event counter
NO
804
Clear phase 0 event counter
Is this event the third phase0 event in a row?
811
NO
YES
813
End event recording loop subroutine

FIG 8

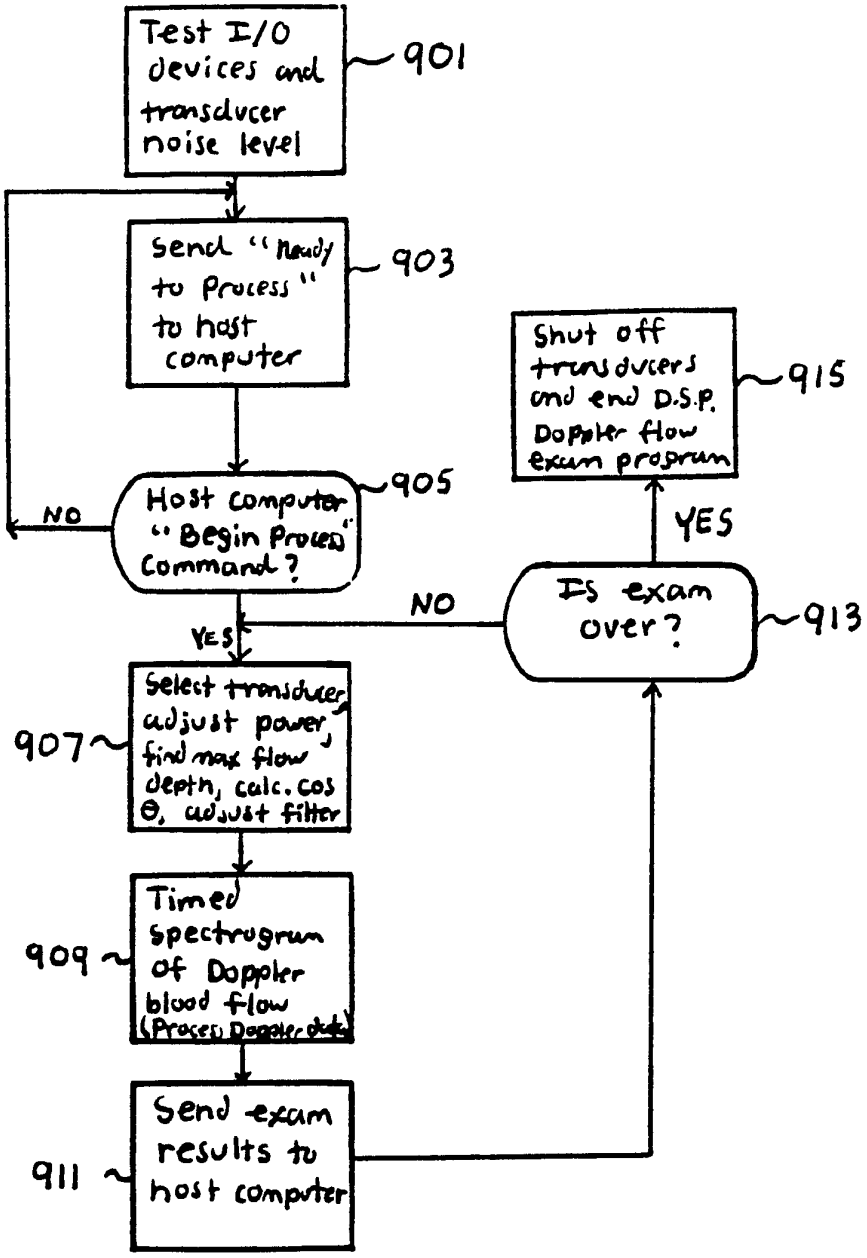

Test I/O devices and transducer noise level
901
Send "Ready to Process" to host computer
903
Host computer "Begin Process" Command?
905
NO
YES
Select transducer, adjust power, find max flow depth, calc. cos θ, adjust filter
907
Timed spectrogram of Doppler blood flow (Process Doppler data)
909
Send exam results to host computer
911
Is exam over?
913
NO
YES
Shut off transducers and end D.S.P. Doppler flow exam program
915

FIG 9

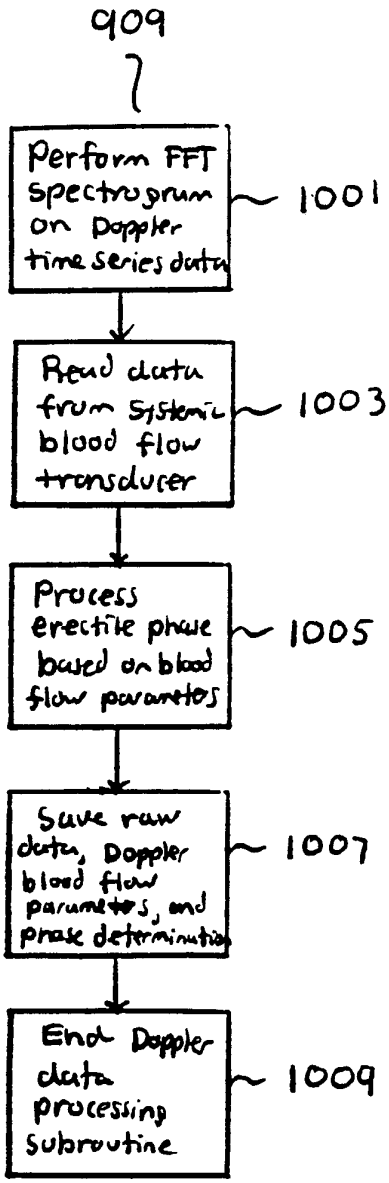

909
Perform FFT spectrogram on Doppler time series data
1001
Read data from systemic blood flow transducer
1003
Process erectile phase based on blood flow parameters
1005
Save raw data, Doppler blood flow parameters, and phase determination
1007
End Doppler data processing subroutine
1009

FIG 10

FIG. 11

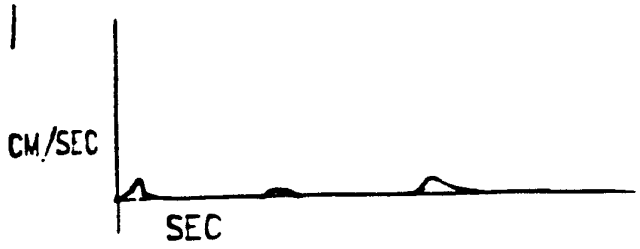


FIG. 12

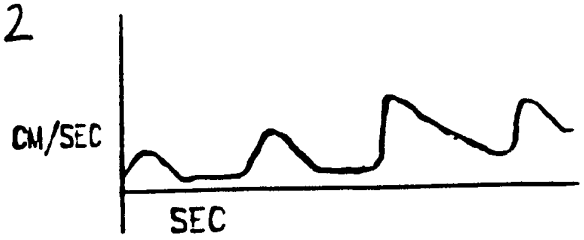


FIG. 13

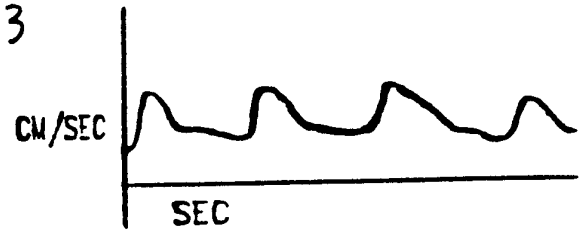


FIG. 14

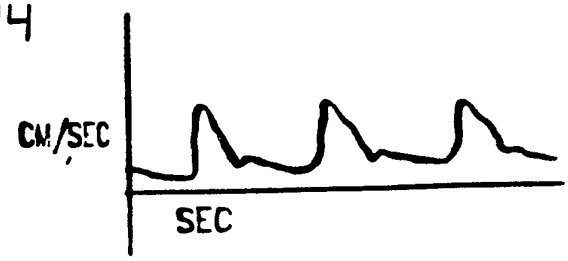


FIG. 15

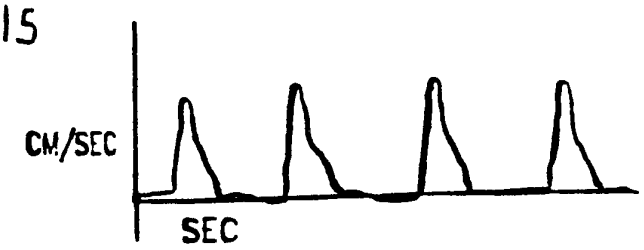


FIG. 16

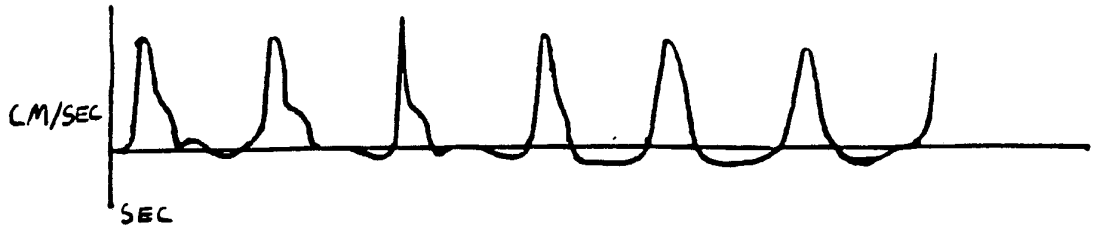


FIG. 17

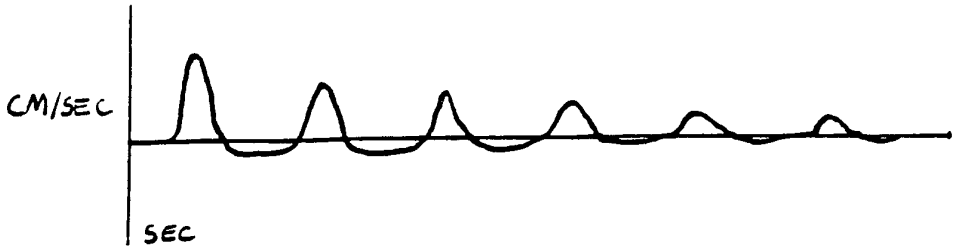


FIG. 18

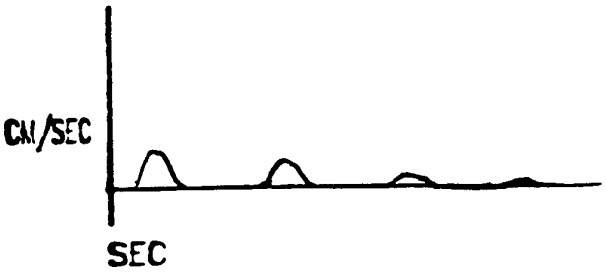


FIG. 19

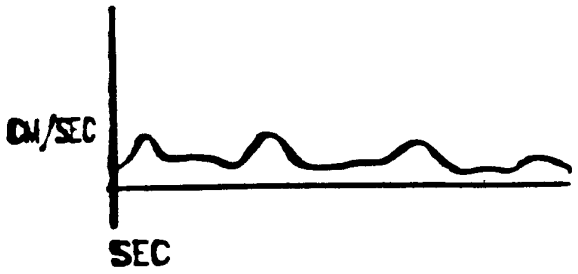


FIG. 20

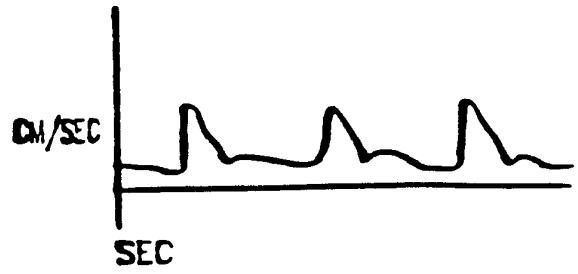


FIG. 21

INTERNATIONAL SEARCH REPORT

International Application No PCT/US91/08965

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

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

IPC (5): G06F 15/42
U.S.Cl.: 364/401

II FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U.S.Cl.	364/413.01 - .02; 413.113,413.13 128/667,668-670

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
Y	FR, A, 2,627,375 (NORRIS) 25 August 1989 See Abstract.	1-21
Y	CH, A, 671,505 (GABLER) 15 September 1989 See Abstract.	1-21
Y	US, A, 4,770,184 (GREENE, JR. ET AL.) 13 September 1988 See Abstract.	14,18,19-20
A	Journal of Urology, Vol. 123, 1980, Velcek et al. See the entire document.	1-21
A	US, A, 4,651,748(VINOGRADOV ET AL.) 24 March 1987 See Abstract.	1-21
A	US, A, 4,281,645 (JOBSIS) 04 August 1981 See Abstract.	1-21
A	US, A, 4,494,550 (BLAZEK ET AL.) 22 January 1985 See Abstract.	1-21

* Special categories of cited documents: [10]

"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	Date of Mailing of this International Search Report
02 February 1992	08 APR 1992

International Searching Authority	Signature of Authorized Officer
ISA/US	INTERNATIONAL DIVISION Gail Hayes

Form PCT/ISA/210 (second sheet) (Rev.11-87)