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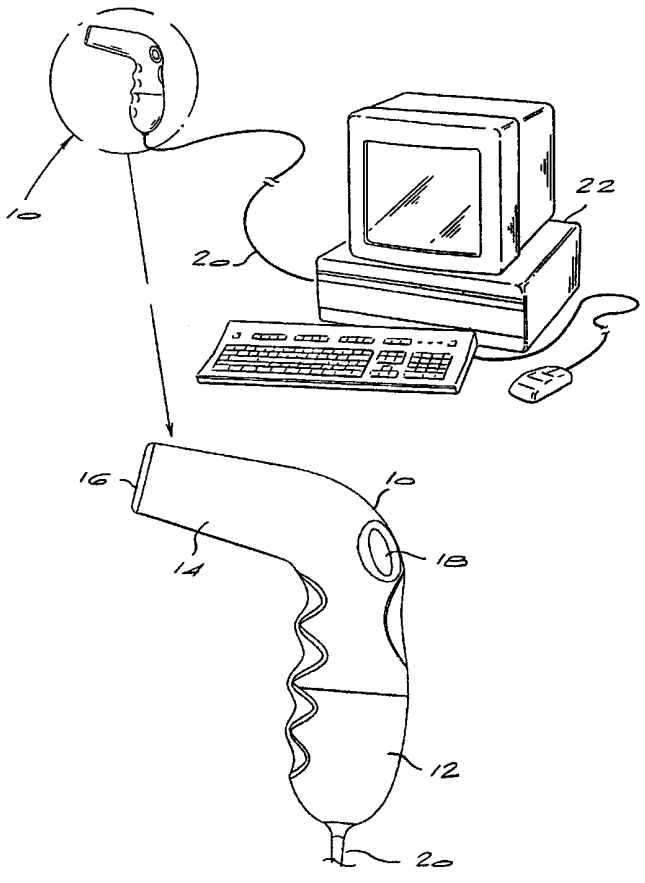
(54) Title: DOPPLER ULTRASOUND APPARATUS



(57) Abstract: An ultrasound probe (10) comprises a hand holdable body (12) with ultrasonic transducers (26, 28) in its head (14), and an electronic circuit which generates an ultrasound signal (40) for transmission into the body of a patient. The reflected ultrasound signal is processed to generate audio band in-phase and quadrature outputs, which are fed to an external signal processing system, typically comprising a conventional PC (22) running suitable software, which generates a characteristic wave form of pulsative blood flow in the body of the subject.

WO 00/74569 A1

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DOPPLER ULTRASOUND APPARATUS

BACKGROUND OF THE INVENTION

THIS invention relates to ultrasound measurement apparatus which can be used, in particular, to measure foetal blood flow.

Sophisticated Doppler ultrasound measuring apparatus is available for the measurement of foetal blood flow. Such measurements provide important information, for example concerning placental dysfunction and compromised foetal development, enabling abnormalities to be identified and attended to.

Equipment of the above kind is generally expensive and therefore not readily available to smaller institutions such as clinics.

It is an object of the invention to provide alternative ultrasound apparatus.

SUMMARY OF THE INVENTION

According to the invention there is provided ultrasound measurement apparatus comprising:

a probe comprising a housing having a grip portion and a head portion supporting transducer means;

drive means in the housing arranged to drive the transducer means with an ultrasound signal for transmission into the body of a subject and reflection to the transducer means;

first signal processing means in the housing arranged to receive a reflection signal from the transducer means and to generate in-phase and quadrature outputs therefrom; and

second signal processing means external to the housing and connectable to the first signal processing means, the second signal processing means being responsive to the in-phase and quadrature outputs to generate a characteristic waveform of pulsative blood flow in the body of the subject.

The transducer means may comprise first and second transducers arranged as a transmitter and a receiver, respectively.

The first and second transducers may be piezoelectric transducers located on an inner surface of a window in the head portion of the housing.

Preferably, the window is formed from a material having an acoustic impedance which lies between that of human tissue and that of the piezoelectric tranducers.

The first signal processing means preferably includes in-phase and quadrature mixers arranged to generate respective in-phase and quadrature output signals at audio frequencies.

The second signal processing means may be connected to the first signal processing means within the housing via a signal cable.

The signal cable preferably includes conductors arranged to supply power to the drive means and the first signal processing means in the housing from a power supply external to the housing.

The second signal processing means may include at least one analog to digital converter for digitising the in-phase and quadrature outputs of the first signal processing means.

Said at least one analog to digital converter may be provided on a sound card associated with a personal computer.

Alternatively, the first signal processing means may include at least one analog to digital converter, such as a Universal Serial Bus (USB) codec, arranged to convert the in-phase and quadrature outputs of the probe to a digital signal.

The second signal processing means preferably includes a software controlled processor for calculating respective power spectra of the in-phase and quadrature signals.

The software controlled processor may be arranged to extract frequency spectrum data from the in-phase and quadrature signals, to detect peaks in the frequency spectrum data, and to calculate blood flow information from changes in the frequency of the detected peaks.

The second signal processing means preferably includes output means for generating a video display of the power spectra and related data.

The second signal processing means may be associated with or comprised by a personal computer (PC) or similar computing means.

The second signal processing means preferably includes an audio circuit for generating an audible signal from the in-phase and quadrature signals, for assisting an operator in positioning of the probe.

The housing may be generally pistol-shaped, with the head portion supporting the transducer means extending transversely from the grip portion.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side view of a prototype ultrasound probe of apparatus according to the invention with an associated personal computer (PC);

Figure 2 is a simplified schematic sectional view of a pair of transducers of the probe of Figure 1;

Figure 3 is a simplified schematic block diagram of the electronic circuitry of the probe shown in Figure 1; and

Figure 4 is a simplified schematic block diagram of signal processing circuitry for use with the probe.

DESCRIPTION OF AN EMBODIMENT

The present invention was developed as an alternative to expensive, highly sophisticated Doppler ultrasound equipment for placental function assessment. The apparatus was designed to permit a trained medical person such as a clinical assistant or nursing sister to assess placental function in a simple and non-invasive manner. Essentially, this is done by providing a convenient, ergonomically designed hand held probe which contains onboard electronics for generating output signals which can be output to a dedicated card or a standard input of an otherwise conventional personal computer (PC), running suitable software, for analysis, display and storage. By using existing computer components such as graphics and interface modules, technology development and system costs are minimised.

It will be appreciated that although the embodiment of the invention described below was designed specifically for placental function assessment, it can be adapted to other medical applications and the described embodiment is merely exemplary.

Referring to Figure 1, the illustrated probe 10 has a grip portion 12 shaped to fit the hand of a user comfortably, and a head portion 14 which extends approximately at right angles from the grip portion, so that the probe is generally pistol shaped. At the tip of the head portion 14 is a window 16 of polymer material which supports a transducer assembly. A control switch 18 is located at the upper end of the grip 12 where it meets the head 14, and is located so as to be easily operable by the thumb of a user. (Alternatively, a separate control unit, operable by the user's other hand, could be provided.) A multi-conductor cable 20 connects the probe to an external signal processing circuit and power supply located in, or associated with, a personal computer (PC) 22.

The housing has an ergonomic shape which is designed to be comfortable both for the operator and the patient in use. The shape of the housing is designed to allow the operator to hold the probe with minimal hand muscle pressure, so that examining a large number of patients should not cause cramping and associated problems arising from continuous gripping of the probe. The use of a cast polymer material such as polyurethane for the housing provides the required mechanical strength.

Referring to Figure 2, the window 16 is shown schematically in section. Located on the inner surface 24 of the window is a transducer assembly comprising a piezoelectric transmitter 26 and a piezoelectric receiver 28 which are fixed to the surface 24 by means of a suitable adhesive. Instead of piezoelectric elements, other suitable electro-mechanical transducers could be used.

The transmitter and receiver are designed to operate at a suitable frequency for the intended application. For foetal umbilical cord analysis, a suitable frequency might be in the region of 4MHz, for example.

The transmitter and receiver of the prototype unit were designed to operate at 4 MHz. The transmitter 26 and the receiver 28 are connected to an electronic circuit via respective cables 30 and 32.

The piezoelectric elements of the transmitter 26 and the receiver 28 are bonded to the inside surface of an appropriate housing before being fixed to the inner surface of the polymer window 16. Alternatively, the transmitter 26 and the receiver 28 could be attached to the inner surface of the window during manufacturing of the window. The piezoelectric elements could be monolithic or composite structures, and will typically be air backed.

The electronic circuit of the probe is shown in a highly simplified schematic form in Figure 3, and in greater detail in the circuit diagram of Figure 5. The circuit includes a power supply module 34 which receives direct current via the multi-conductor cable 20 and regulates and filters it before supplying the electronic components of the probe.

In a nutshell, the probe is used to generate an ultrasonic frequency which is output via a first transducer into the body of a patient. Reflected ultrasonic energy is received by a second transducer, amplified and mixed with a master clock and quadrature clock signal to provide Doppler quadrature frequency outputs in the audio band, which are output to an external or remote signal processing circuit.

The theory of operation of the apparatus of the invention is briefly as follows.

A high frequency Continuous Wave ultrasound signal (typically at 4 MHz) is transmitted from the probe. By placing the probe on the patient's body and directing towards a blood vessel the ultrasound signal will be back-scattered from the blood corpuscles. The movement of the corpuscles causes the ultrasound signal to be shifted in frequency. This shift in frequency is proportional to the movement (velocity and direction) of the blood corpuscles and hence blood flow can be determined from the Doppler equation:

$$F = \frac{2 v f \cos\theta}{C}$$

Where

F is the Doppler frequency shift

v is the blood velocity

f is the probe transmission frequency

C is the speed of sound in tissue

θ is the relative angle of the ultrasound signal and the blood flow direction.

Note that the probe is held stationary in use.

The Doppler frequency information received is not a unique frequency but a band of frequencies which are made up from the relative velocities and angles that the blood corpuscles present. Note that the individual blood cells are too small to present a reflection individually but at low shear rates they join together to form a rouleaux which breaks as the shear rate increases. Over the cross section of the blood vessel under investigation there is a spread of velocities from almost zero at the vessel walls to maximum in the centre. Also, the flow is non laminar and therefore the direction and relative angle of the target cells is random and varied. The net result is a spectrum of Doppler frequencies within the target zone for every systole/diastole cycle.

To extract the Doppler quadrature (I and Q) signals required for the processing the received high frequency signals are mixed down to base band. This is to simplify the analysis and the transmission of the signals. It is therefore necessary to mix the received signal with the respective reference phase to begin the I and Q processing. This process is similar to the demodulation of frequency modulated radio signals:

$$\cos x.\cos y = \tfrac{1}{2}(\cos(x+y)+\cos(x-y))$$
$$\sin x.\cos y = \tfrac{1}{2}(\sin(x+y)+\sin(x-y))$$

By the use of a high pass filter the cos(x+y) and sin(x+y) components can be eliminated. The Doppler frequency F remains and also the in-phase and quadrature outputs are determined.

I.....1/2 cos(x-y)

Q.....1/2 sin(x-y)

The probe circuit includes a crystal oscillator circuit 36 which generates a 16 MHz square-wave clock pulse. The oscillator output is fed to a phase generator circuit 38 consisting of a pair of D type flip-flops which generate quadrature clock signals at 4 MHz, 90° apart. These signals are the reference clock frequencies within the probe. The 16 MHz master clock frequency is buffered and amplified by a drive circuit 40 before being fed to the transducer 26 which acts as a transmitter, and which converts the electrical drive signal to ultrasonic acoustic energy. This energy is input to a patient's body with which the window 16 of the probe is in contact. In this regard, the material of the window 16 provides an acoustic matching layer designed to optimise the operation of the transducers. The acoustic impedance of the matching layer should lie between that of human tissue and the piezoelectric material in order to optimise the transfer of energy through the matching layer. It was found that a cast polymer such as polyurethane has a suitable density for the matching layer.

The reflected ultrasonic signal from the patient's body is detected by the transducer 28, the output of which is fed to an RF preamplifier 42. The preamplifier output is fed to respective in-phase and quadrature mixers 44 and 46 which are fed with the two phase-shifted clock signals from the phase generator 38. The outputs of the mixers 44 and 46 are the respective Doppler quadrature frequency outputs I and Q which are filtered by respective low pass filters 48 and 50 to remove components above the audio band. The I and Q signals are buffered by respective operational amplifiers 52 and 54 before being output via the multi-conductor cable 20 to the PC 22.

Although the material of the probe housing is typically a plastics polymer, the interior surface of the housing can be coated with a conductive material such

as graphite with additional screening layers of tin, copper or beryllium copper foil, for example, to provide extra screening around the higher frequency components, thus limiting the susceptibility of the apparatus to electromagnetic interference and also reducing its electromagnetic emissions.

Figure 4 shows the signal processing circuit which is implemented remotely from the probe 10, *inter alia* utilising the PC 22. Together with a suitable data capture card, which could be a conventional computer sound card, the PC 22 operates as a digital signal processor to generate meaningful information from the output signals of the probe 10.

In a nutshell, the remote or outboard data processing unit receives audio frequency signals from the probe 10 and by various signal processing methods converts these signals into a characteristic waveform of pulsative blood flow. Filtering removes the unwanted components of the received signal so that averaging and other statistical analysis can be used to determine the resistive index (RI) and other pertinent information. An audio output is generated from the received signal to allow an operator to optimise the positioning of the probe for the examination. The characteristic waveforms are displayed on a monitor to allow the operator to assess the information presented and to make certain adjustments to the unit, such as the filtering employed. The apparatus is able to present the information in multiple formats, such as a historical chart of previous examinations to allow tracking of the measurements to be undertaken. The unit also has the capability to output the data in a hard copy format.

The I and Q output signals of the probe are fed to first and second analog to digital converters 56 and 58. The A/D converters are set up to sample their respective signals simultaneously, since the phase of the I and Q channels is required to extract the positive and negative frequency components. The returned or reflected signal typically has a maximum Doppler shift frequency of

4 kHz. A safety factor of 4, to account for variations in probe angle, blood flow and waveform pulsatility is used, so that Doppler shifts of up to 16 kHz can be handled. The A/D converters can sample each channel at a frequency of greater than 32 kHz, at a resolution of 16 bits per channel, which is sufficient for the required range.

Assuming that the frequency spectrum of the signal can be regarded as stationary for a period of 10ms, all sampling and processing for a given reading must be carried out within this period. Assuming that a sampling frequency of 32 kHz is used, 320 signal samples can be taken in 10ms. In order to provide time for further processing, as well as suitable data for a Fast Fourier Transform, 256 samples are used, which requires 8ms.

In software, Hamming windows 60 and 62 are implemented on the A/D converter outputs to reduce the noise due to the finite sampling period.

Due to the presence of a large component of backscatter from the surrounding tissue in the received signal from the probe, a pair of high pass wall filters 64 and 66 are provided to reduce noise and increase dynamic range. The backscatter component is at very low frequencies and can be 40 dB greater than the backscatter from the blood rouleaux forming the blood flow targets of the probe. The filters have a cut-off frequency of 50 Hz to avoid distortion of the signal.

For ease of implementation and speed of calculation, an IIR filter, instead of a FIR filter, is used. The passband is 40 dB above the stopband and maximally flat to avoid distortion of the power spectrum in the passband, and to prevent the wall "clutter" from being greater than the blood's rouleaux backscatter. The linearity of the phase response is not important, but care has been taken that both channel filters' phase response be the same, to preserve the relative phase information. An Inverse Chebyshev (Chebyshev Type II) filter is used.

Before the frequency components of the Q channel can be added to or subtracted from those in the I channel, they must be phase shifted by 90°. A Hilbert transform routine 68 is used to achieve this. By treating the I and Q channel as imaginary signals, then multiplying the Q channel by the imaginary number *j*, resulting in the real part of *j*Q being the 90 degree shifted version of the real part of Q. The positive frequency components are then extracted by performing a complex FFT on I+*j*Q and the negative frequency components from I-*j*Q. This is the most computationally efficient algorithm to use.

After the I and Q channels have been added and subtracted from one another in the time domain by operational amplifiers 70 and 72, the frequency data of the signal has to be extracted. This is achieved in power spectrum routines 74 and 76 which multiply the complex Fast Fourier Transform (FFT) of that signal in a given channel with the complex conjugate of itself which is then scaled appropriately.

The data processing is completed in under 2ms, including all the windowing, filtering 90 degree shifting, FFT's, multiplications and peak detection that have to be performed. The whole data acquisition and processing window is thus less than the required 10ms.

The next step is the implementation of peak detection algorithms 78 and 80 which firstly detect the relevant peak frequencies of the spectrum and then estimate the maximum relevant frequency that occurs above a given threshold value. The resulting flow information is made available for display on a suitable monitor 82. The calculated blood flow information is now available for display, and selected peaks and troughs are identified and averaged to present the required RI index. The relevant audio and processed data can be stored in memory 84 or in file format on the PC.

Due to the fact that different PC sound cards have different specifications, it can be advantageous to carry out the necessary analogue to digital conversion of the I and Q output signals within the probe, so that the probe output is a standardised digital signal. This is conveniently achieved by using a Universal Serial Bus (USB) codec which provides the I and Q output signals in a USB compatible format. Since almost all modern PC's have a USB input, this provides a convenient way of connecting the probe to the PC 22, without the need for adjusting gain settings on a sound card input. The USB port can handle sufficiently high data transfer rates, and also supplies 5 Volts DC, which can be used to power the probe electronics. The USB codec can be implemented as an intermediate device which is connected between the probe and the PC, but is preferably integrated into the electronic circuit of the probe itself.

Although the above described apparatus is intended as a stand alone system for determining the resistive index of umbilical foetal blood flow, the data obtained by the unit may be useful for further medical analysis or for future integration into a computerised or networked patient care system. The use of standard computer technology where possible facilitates networking and sharing of the data acquired. In addition the database 84 contains reference information that the operator can access to enable assessments to be made on individual cases if the need arises. A patient's record can be stored in the database with the patient and operator's name, as well as the time and date for a report. The data is stored in conventional storage media, which can include an optical storage facility. Using a standard printer, a hard copy of the report and/or the scan results can be generated.

CLAIMS:

1. Ultrasound measurement apparatus comprising:

a probe comprising a housing having a grip portion and a head portion supporting transducer means;

drive means in the housing arranged to drive the transducer means with an ultrasound signal for transmission into the body of a subject and reflection to the transducer means;

first signal processing means in the housing arranged to receive a reflection signal from the transducer means and to generate in-phase and quadrature outputs therefrom; and

second signal processing means external to the housing and connectable to the first signal processing means, the second signal processing means being responsive to the in-phase and quadrature outputs to generate a characteristic waveform of pulsative blood flow in the body of the subject.

2. Ultrasound measurement apparatus according to claim 1 wherein the transducer means comprises first and second transducers arranged as a transmitter and a receiver, respectively.

3. Ultrasound measurement apparatus according to claim 2 wherein the first and second transducers are piezoelectric transducers located on an inner surface of a window in the head portion of the housing.

4. Ultrasound measurement apparatus according to claim 3 wherein the window is formed from a material having an acoustic impedance which

lies between that of human tissue and that of the piezoelectric transducers.

5. Ultrasound measurement apparatus according to any one of claims 1 to 4 wherein the first signal processing means includes in-phase and quadrature mixers arranged to generate respective in-phase and quadrature output signals at audio frequencies.

6. Ultrasound measurement apparatus according to any one of claims 1 to 5 wherein the second signal processing means is connected to the first signal processing means within the housing via a signal cable.

7. Ultrasound measurement apparatus according to claim 6 wherein the signal cable includes conductors arranged to supply power to the drive means and the first signal processing means in the housing from a power supply external to the housing.

8. Ultrasound measurement apparatus according to any one of claims 1 to 7 wherein the second signal processing means includes at least one analog to digital converter for digitising the in-phase and quadrature outputs of the first signal processing means.

9. Ultrasound measurement apparatus according to claim 8 wherein said at least one analog to digital converter is provided on a sound card associated with a personal computer.

10. Ultrasound measurement apparatus according to any one of claims 1 to 7 wherein the first signal processing means includes at least one analog to digital converter arranged to convert the in-phase and quadrature outputs of the probe to a digital signal.

11. Ultrasound measurement apparatus according to claim 10 wherein said at least one analog to digital converter comprises a Universal Serial Bus (USB) codec.

12. Ultrasound measurement apparatus according to any one of claims 1 to 11 wherein the second signal processing means includes a software controlled processor for calculating respective power spectra of the in-phase and quadrature signals.

13. Ultrasound measurement apparatus according to claim 12 wherein the software controlled processor is arranged to extract frequency spectrum data from the in-phase and quadrature signals, to detect peaks in the frequency spectrum data, and to calculate blood flow information from changes in the frequency of the detected peaks.

14. Ultrasound measurement apparatus according to claim 12 or claim 13 wherein the second signal processing means includes output means for generating a video display of the power spectra and related data.

15. Ultrasound measurement apparatus according to any one of claims 1 to 14 wherein the second signal processing means is associated with or comprised by a personal computer (PC) or similar computing means.

16. Ultrasound measurement apparatus according to any one of claims 1 to 15 wherein the second signal processing means includes an audio circuit for generating an audible signal from the in-phase and quadrature signals, for assisting an operator in positioning of the probe.

17. Ultrasound measurement apparatus according to any one of claims 1 to 16 wherein the housing is generally pistol-shaped, with the head portion

supporting the transducer means extending transversely from the grip portion.

Fig 1

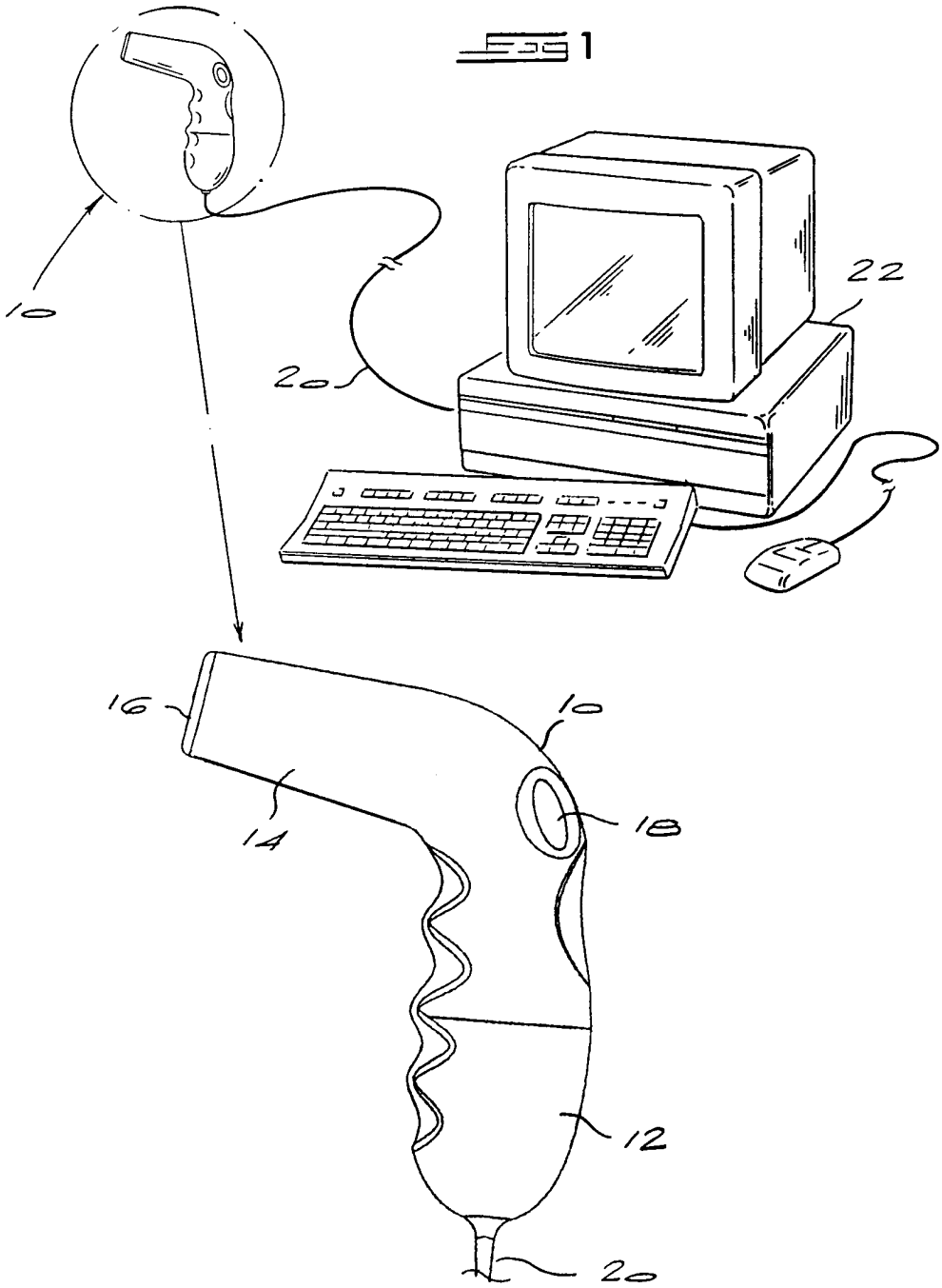


Fig 2

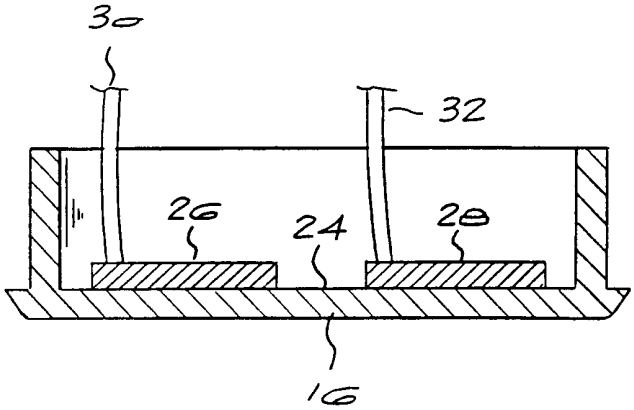
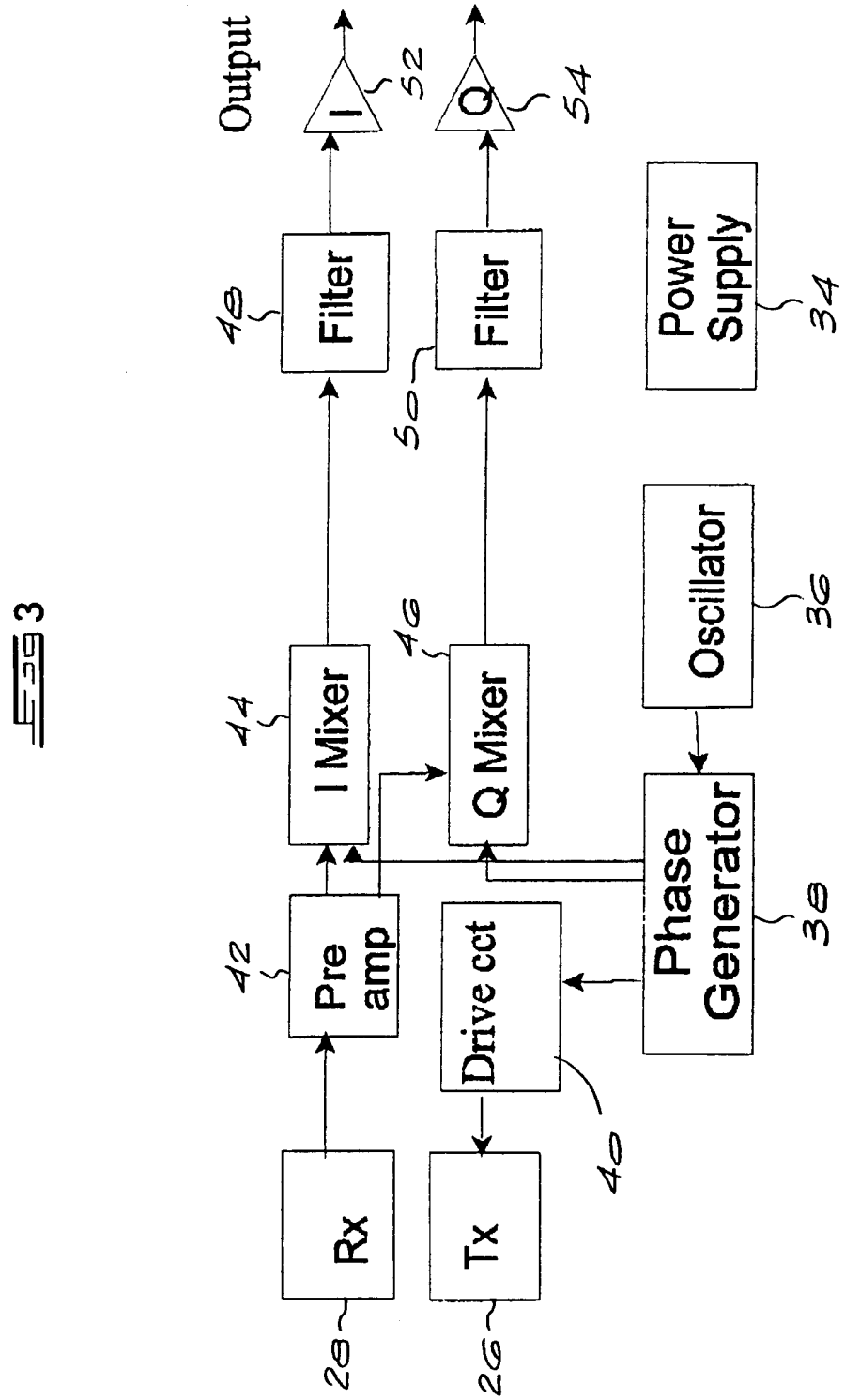


Fig 3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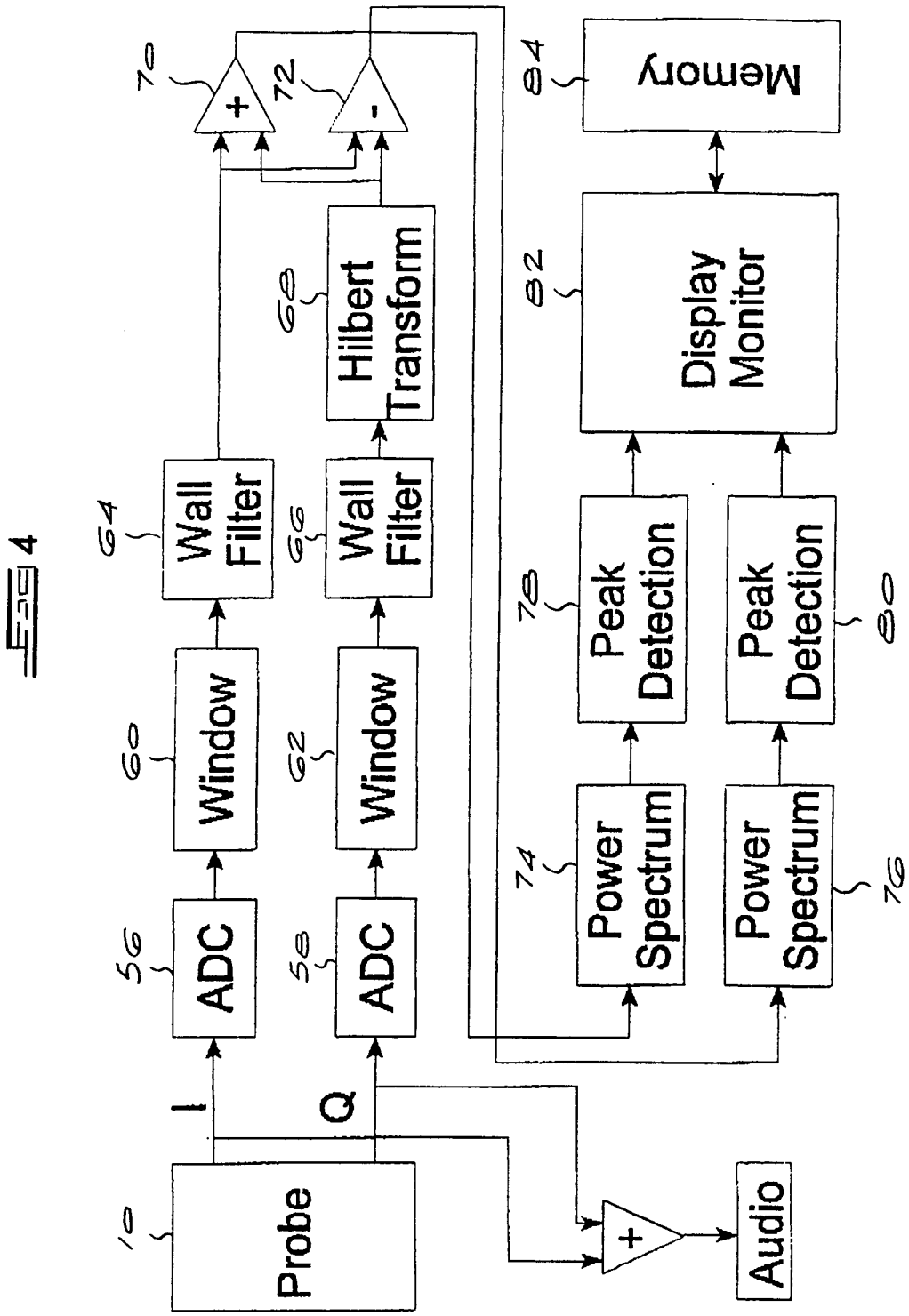
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Wall Filter
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Wall Filter
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+
70
-
72
Power Spectrum
74
Power Spectrum
76
Peak Detection
78
Peak Detection
80
Display Monitor
82
Memory
84
+
Audio

FIG 4

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 00/00759

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B8/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	US 5 749 831 A (D.A. BAKER) 12 May 1998 (1998-05-12) column 3, line 29 - line 61 column 7, line 24 -column 8, line 6 column 12, line 57 -column 13, line 27 --- -/--	1,2,6-9, 14,15

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"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

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 September 2000	12/09/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Rieb, K.D.

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Intern. ..nal Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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Information on patent family members

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