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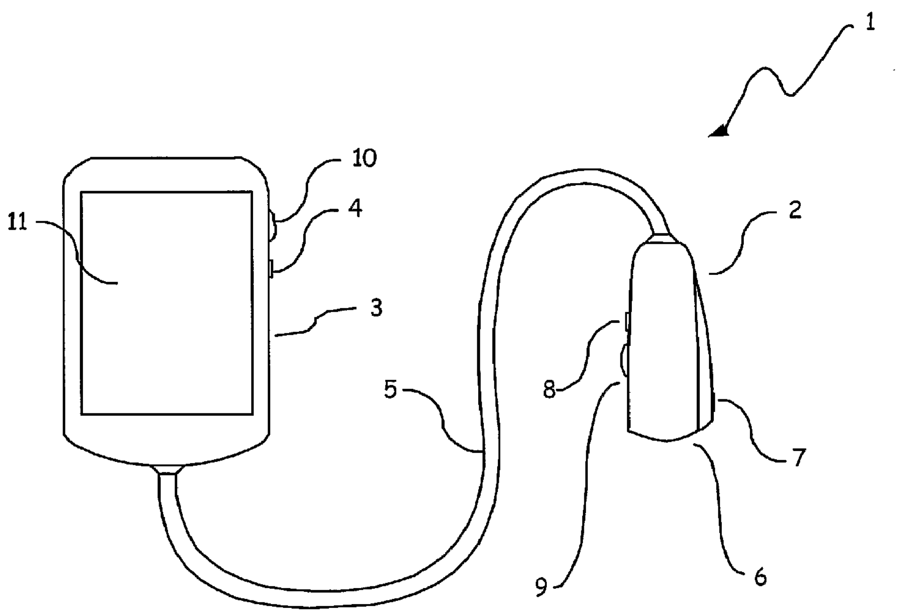

(57) Abstract: An ultrasound measurement system including a handheld display and processing means, an ultrasound transducer a processing means of a substantially similar weight to the handheld display and processing means and a transmission cable interconnecting the handheld display and processing means with the ultrasound transducer and processing means, the cable being of sufficient length to provide a means to mechanically locate the system around the neck of user.

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ULTRASOUND MEASUREMENT SYSTEM AND METHOD

FIELD OF THE INVENTION

The present invention relates to a low cost and efficient medical ultrasound imaging, measurement and recording system with a configurable interface that supports a variety of medical ultrasound probes.

BACKGROUND OF THE INVENTION

Ultrasound was first investigated as a medical diagnostic imaging tool in the 1940's. George Ludwig was the first scientist to use amplitude mode (A-mode) ultrasound to detect foreign bodies in tissue. This is described in the report by Ludwig et al., "Considerations underlying the use of Ultrasound to detect Gallstones and Foreign Bodies in Tissue", *Naval Medical Research Institute Reports*, Project #004 001, Report No. 4, June 1949. In the early 1950's Wild and Reid constructed a B-mode scanning system using a mechanically mounted rotating transducer, described in Wild, J.J. and Reid, J.M. (1952) "Application of echo-ranging techniques to the determination of structure of biological tissues". *Science* 115:226-230 (1952). Ultrasound technology developed significantly in the 1960's with the development of articulated arm B-mode scanners by Wright and Meyerdirk (US Patent No. 1970000062143). Articulated arm scanners, also known as static mode scanners, connect the ultrasonic transducer to a moveable arm, with movement of the arm mechanically measured using potentiometers. Static mode ultrasound scanners were in wide use until the early 1980s. The static mode scanners were large cumbersome devices, and the techniques used are not readily suited to a handheld ultrasound system.

In the mid 1970's real-time scanners were developed where an ultrasonic transducer was rotated using a motor. Krause (US Patent No. 3470868 – Ultrasound diagnostic apparatus) describes an invention where a motor rotates an ultrasonic transducer in order to produce images in real-time. The clinical usefulness of such real-time B-mode scanners is outlined in the article by J.M Griffith and W.L Henry titled "A sector scanner for real-time two-dimensional echocardiography". *Circulation* 49:1147, 1974. The nature of these devices, as well as the motor driving circuitry, adds size, power consumption, and cost to the device. Additionally, the motor itself and associated moving parts reduces the reliability of the device.

The further development of ultrasound resulted from developments in electronic beam steering transducers. Wilcox (US Patent No. 3881466) describes an invention consisting of a number of electronic crystals where the transmitting pulse can be delayed in sequence to each crystal and effect an electronic means to steer the ultrasound beam. The basic technique is still in wide use today, with nearly all modern medical ultrasound equipment using an array of ultrasonic crystals in the transducer. The early designs used at least 64 crystals, with modern designs sometimes using up to a thousand crystals or more.

Electronic beam steering removes the need for a motor to produce real time images, but the cost of producing transducers with arrays of crystals is high. The transducers are usually manually manufactured, with the channels having excellent channel to channel matching and low cross-talk. The probe cost is not an important factor in state-of-the-art ultrasound diagnostic systems, as the overall equipment cost is several times the probe cost. The power consumption for electronic systems is also high, and is generally proportional to the number of channels being simultaneously operational.

Much of the prior art in ultrasound technology is directed to improving the performance of ultrasound systems enabling them to be used for an ever increasing range of diagnostic applications. The result has seen significant advances in ultrasound systems with transducers using ever increasing numbers of crystals, and host systems with ever increasing processing power. The result has seen systems with 3D and real-time 3D (or 4D) capability.

Some manufacturers have focussed on producing systems which are more portable than the large and bulky systems used in radiology clinics and large hospitals. Sonosite have developed products able to be hand-carried (US Patent No. D461895, 6575908) using transducer with arrays of crystals. The cost and power consumption of the Sonosite systems is far less than the large cart based systems, but still too expensive for most primary care physicians. Chiang et al (US Patent No. 5590658, 5690114, 5839442, 5957846, 6106472) disclose a system with a beamforming array using charge domain processing connected to a host processing unit via a high speed interface. The preferred embodiment connects to a laptop computer, however those skilled in the art would understand the device could be connected to a handheld processing system. Halmann et al (US Patent No. 7115093) of General Electric disclose a similar device, specifically intended for use with a handheld processing system, which uses digital beamforming. However, both products still consist of expensive and power hungry multi-element transducer arrays resulting in a costly imaging system. Other hand-carried ultrasound systems are available from General Electric (Logiqbook family) and several other vendors, with a common characteristic of the devices being their inclusion of a multi-element transducer and a laptop sized processing system.

The hand carried ultrasound systems are improving in performance and are able to be used in diagnostic procedures only a short time ago limited to the larger cart based ultrasound systems. Sonosite claim the Micromaxx hand carried unit "represents the technology crossover point between hand-carried ultrasound and larger, high-performance, cart-based systems." The trend has been for hand-carried ultrasound to improve where it can perform most of the diagnostic functions currently performed by more expensive cart based systems. The result is an increase in the cost of hand-carried systems, rather than a decrease.

Several inventors have investigated methods of reducing the cost of the transducers, although not necessarily for use with a handheld ultrasound system. Sliwa and Baba (US Patent No. 5690113) proposed a system where a stationary ultrasound transmitter coupled with position and orientation sensing circuitry are combined to form an inexpensive ultrasound probe. The system claims a non-real time ultrasound system consisting of either untethered probes with wireless communications or a tethered probe with an electromagnetic receiver mechanically coupled to the probe, and a separate electromagnetic transmitter providing a reference position signal. The probe could be manufactured cheaply enough to be disposable, reducing requirements for a sterilisation procedure between examinations and is especially suited to intra-uterine examinations. The requirement for the tethered transducer to have a separate stationary electromagnetic transmitter is well suited to cart or desk based systems, where the host processing unit does not move, but is not suitable for handheld systems where the host processing unit is moving. The requirement for a wireless communications system in the probe increases cost and power consumption, requiring additional components for the wireless communications system and a separate battery for the ultrasound probe.

Hunt et al broadly disclose an invention (US Patent No. 6780154) consisting of a segmented ultrasound system consisting of an ultrasound processor and transducer connected to a wireless handheld computing device. The ultrasound processor and transducer construct an image and wirelessly communicate the image to a display device in non-real time. The limitation of the invention is no low cost method is proposed to construct the ultrasound image, with the preferred embodiment being a 64 channel array. The system also requires a separate battery supply for the ultrasound processor and transducer, and incurs the overhead of the wireless communications scheme in power consumption limiting the battery life and utility of the device.

There is a need to improve on the prior art by constructing a handheld ultrasound system of low power consumption, low cost, low weight, of small size, and easy to use such that it can be used by primary care physicians.

SUMMARY OF THE INVENTION

In accordance with a first aspect of the present invention, there is provided an ultrasound measurement system including: a handheld display and processing means; an ultrasound transducer and processing means of a substantially similar weight to the handheld display and processing means; and a transmission cable interconnecting the handheld display and processing means with the ultrasound transducer and processing means and being of sufficient length to provide a means to mechanically locate the system around the neck of a user.

Preferably, the handheld display and processing means includes a primary user input means and the ultrasound transducer and processing means includes a secondary user input means. Preferably, the primary user input means consists at least of a scroll wheel and push activated buttons, and the secondary user input means consists of a scroll wheel and push activated buttons. Preferably, the system also includes an ultrasonic transmit and receive means, and a position and orientation measuring means in order that the received ultrasound signals can be displayed in spatial register with each other. Preferably, the ultrasound transducer means further includes a non-volatile memory for storing position and orientation calibration data.

Preferably, the ultrasound transducer means includes a means for processing the position and orientation data and the calibration data and producing normalized position and orientation data. Further, the display and processing means can comprise a microphone and software means for recording user voice (dictation). The display and processing means can incorporate a communications means for connecting and sending recorded data to/from other systems for importing or exporting patient data. The display and processing means can include an integrated camera for recording images. The ultrasound transducer and processing means can include a gel dispensing means with a replaceable gel cartridge.

Preferred embodiments broadly disclose novel systems in which ultrasonic measurement and imaging can be conveniently performed with less complexity and cost than previously available devices. The preferred embodiment devices possess a range of novel characteristics whereby the cost of medical ultrasound scanning is significantly and advantageously reduced and which also enhances the ease of use and convenience of their operation to the level at which they are operable by a primary care physician.

Preferred embodiments of the invention include a handheld display and user input host system connected to an ultrasound transducer via a cable. The handheld display system and the ultrasound transducer system are manufactured to be of similar volume and mass, facilitating a balanced load when the system is carried around a user's neck or over a user shoulder. The systems and cable are also of a size to be conveniently folded and placed in a user's pocket.

The ultrasound transducer system consists of one or more elements for transmitting and receiving ultrasonic waves with associated transmission circuitry and receiver amplifiers. The receiver circuitry includes analog to digital converters for converting the electrical representations of the received ultrasonic energy to digital data.

The ultrasound transducer system also contains a controller for communicating with the host system, controlling operation of the ultrasound apparatus, and accepting user inputs from local mechanical or electrical switches and user input means. A preferred embodiment also contains circuitry for measuring the orientation and/or position of the transducer relative to a starting point or external reference, a temperature sensor, and a means to store local calibration data. The position/orientation measurement data is processed with the calibration data according to the temperature and input, and combined with the ultrasound data before being transmitted over the cable to the host system, enabling a position measurement system of high accuracy without the host system being aware of the means of position measurement. The position and orientation measurement allows an ultrasound transducer where the transmission pulse is transmitted in a fixed relative position to the ultrasound transducer, but moved in space by the user moving the probe.

The ultrasound transducer system can include an ultrasound gel storage and dispensing system, removing the requirement to carry a bottle of ultrasound gel, and a camera, for recording scan locations.

The host processing and display system is of a size able to be conveniently held and controlled using a single hand. In a preferred embodiment, the processing and display system can be held in one hand and all functionality controlled using the users thumb. The second hand is free to hold and manipulate the ultrasound transducer. Alternatively, the host processing and display system can be mounted on a users arm using a strap freeing the first hand for other use. The second hand is free to hold and manipulate the ultrasound probe, and use the ultrasound probes secondary user input means to control the basic ultrasound functionality. The system can be configured to use position and orientation measurement circuitry in the ultrasound unit to generate user interface position information for "mouse" type operation.

The host processing and display system could advantageously contain communications components such as those enabling wireless network communications, and software enabling the interfacing to host computers or servers containing medical records databases, providing a simple and convenient means for transferring patient data to an electronic records system.

BRIEF DESCRIPTION OF THE DRAWINGS

A preferred embodiment of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

Fig. 1 is a diagrammatic representation of the device.

Fig. 2 illustrates a user using the device.

Fig. 3 illustrates a user with the device resting around their neck.

Fig. 4 is a schematic diagram of one form of the preferred embodiment of the ultrasound system.

Fig. 5 is a schematic diagram of one form of the field programmable gate array (FPGA) utilised in the ultrasound system.

Fig. 6 is a schematic diagram of a second embodiment form of the ultrasound system.

Fig. 7 is a sectional view illustrating details of the ultrasound gel dispenser.

Fig. 8 is a schematic diagram of one form of implementation of the host display and processing unit.

DESCRIPTION OF PREFERRED AND OTHER EMBODIMENTS

The background art provides several devices possessing unwieldy modes of operation. There is a need to integrate more fully the processing, recording, communication, display and control of ultrasound equipment and to reduce its cost and operational complexity such that it can be used by primary care physicians.

The preferred embodiment broadly disclose novel systems in which ultrasonic measurement and imaging can be conveniently performed with less complexity and cost than previously available devices. The preferred embodiment devices possess a range of novel characteristics whereby the cost of medical and veterinary ultrasound scanning is significantly and advantageously reduced and which also enhances the ease of use and convenience of their operation to the level at which they are operable by a primary care physician.

According to the invention there is provided an ultrasonic measurement and imaging system. An example embodiment is illustrated in Fig. 1. The system illustrated by 1 comprises a handheld display and processing system (3) connected to an ultrasound system (2) via a cable (5). The handheld display and processing system (3) and ultrasound system (2) are designed to be of substantially equivalent mass, enabling the system to be conveniently stored around a users neck, enhancing the portability of the device. An example of a user 12 implementing this mode of carriage is illustrated in Fig. 3. The ultrasound system contains an ultrasound tranducer or transducers (6) and a means for storing and dispensing ultrasound gel (7) removing the requirement for a user to carry an addition ultrasound gel dispenser.

The system is typically used by a user for an examination of a patient. The first phase is for setting up patient details. The second phase is ultrasound operation, with the user performing rudimentary user input such as selecting settings, and starting and stopping ultrasound scanning. The final phase is analysis and storage of the collected ultrasound data. To facilitate the different phases of examination, a variety of user input means are provided.

The handheld display and processing system (3) provides a scroll wheel (10) and a button user input means (4) to allow control of most operations.

As illustrated in Fig. 2, the user input means (4) can be operated by a user's thumb or finger when the device (3) is comfortably resting in the user's hand, freeing the second hand to hold and control the ultrasound part of the system (2).

Alternatively, the handheld display and processing system can be mounted on a user's arm using a separate detachable strap/mounting means, freeing the corresponding hand for use in medical procedures such as ultrasound guided vascular procedures. For this operation, the ultrasound system (2) includes a secondary user input means (8 and 9) to control the handheld display and processing system (3).

The above described user input means are suitable for use during operation of the system such as during a patient examination. The first phase and third phase usually are before or after a patient has been examined, and therefore alternative more efficient text input means are provided.

The embodiment provides a stylus with a touch screen 11, and a Bluetooth interface enabling the use of wireless keyboards or input devices. A microphone in conjunction with a "Dictaphone" application can be used for voice recording. An alternative embodiment omits the touch screen but provides a means for interpreting position and orientation measurements in the ultrasound system (2) as part of user input, enabling the ultrasound system (2) to provide a positional (or mouse) style of user input.

Turning now to Fig. 2, there is illustrated a schematic block diagram of the components of the ultrasound system 2. The preferred embodiment of the ultrasound system (2) comprises an ultrasound transducer (13) for transmitting and receiving ultrasound energy in a fixed position relative to the housing. The ultrasound housing can be moved freely by the user with a means provided to measure the relative position and orientation of the ultrasound housing to a starting position. By capturing the received ultrasound energy, and the relative position of the ultrasound housing, the system can recreate a B-mode ultrasound image. The preferred embodiment uses a position and orientation measurement sensor (19) requiring few or no moving parts, such that the embodiment is less affected by reliability issues inherent in prior art which use a motor to move the transducer. A simple system uses solid state gyroscopic circuitry or an arrangement of accelerometers for measuring angular velocity in order to determine the orientation of the ultrasound system relative to a starting point. The inclusion of multiple accelerometers enables displacement to be measured.

A system with three accelerometers and three solid state gyroscopes can measure position and orientation for full 3 dimensional resolution. Much of the prior art discusses the drift problems inherent in accelerometer systems, however this problem is negated by the typical use of the present system. Typically, in use, a user places the ultrasound probe at the location where a scan is required, pointing at the object to be imaged. The user presses a button as part of the user input mechanism (22) to indicate a scan is to begin and holds the probe still. The system provides either audible or visual feedback to indicate a calibration has been successfully completed, and the user sweeps or moves the transducer through the required position and orientations. A scan occurs quickly and thereby limits the drift of the position and orientation system to a level within the systems resolution.

The transducer means (13) consists of one or more sensors for the transmission and reception of ultrasonic signals. For low cost, a single ultrasonic transducer element is provided, with focussing implemented by an acoustic lens or mirror system. Improvements to the system can be achieved at the expense of cost by adding additional transducer elements for transmit and receive operations.

The embodiment provides an ultrasonic system comprising a transmitting section (14) which generates one or more signals which stimulate the transducer means (13) to transmit ultrasound into the body of the patient, a diplexer (15) to protect the receive circuitry during transmission, and a receiving section which converts the ultrasound energy into electricity via the transducer (13) and amplifies (16) the electrical representation of the ultrasonic signals returned from the patient's body via a combination of reflection and refraction. The amplifier (16) typically can include a time-gain compensation amplifier where the gain is increased according to elapsed time from a pulse transmission. The amplified electrical signals are converted to a digital format by an analog to digital converter (17). The transmission of the ultrasound pulse can be initiated by a timing system implemented in a FPGA (18), which can also initiate a measurement of the housing position and orientation via position sensor (19) and temperature via temperature sensor (24). The timing system can be configured to only generate transmission of ultrasound pulses after the position and orientation sensor (19) has detected a change in position greater than a predefined threshold, thus minimising the amount of ultrasound energy and battery power used in the collection of an ultrasound scan. The position and orientation measurement means (19) also has its signal converted to a digital format by analog to digital converters (20) if required.

The FPGA (18) processes the position and orientation data to convert the information to a reference format, combines the data with the captured ultrasound data associated with the same measurement, and transmits the combined information via the interface (23) to the handheld display and processing system for further processing and display. A functional block diagram of the FPGA unit is displayed in Fig. 5.

A systems microcontroller (21 of Fig. 4) can store calibration data for the position and orientation system and the Ultrasound Transducer, which are loaded into corresponding tables 27, 31 in the FPGA 18, enabling an increase in accuracy of the system overall. The calibration data is transferred to the FPGA (18) whenever the ultrasound system is readied for ultrasound scanning, and included in the processing of each individual position measurement. The calibration storage tables 27, 31 provide for the storage of calibration data on the probe enabling a consistent interface format regardless of probe design and construction (i.e. regardless of the arrangement and type of position and orientation means). In one embodiment, the calibration storage table is used in conjunction with a field-calibration process wherein a standard phantom is temporarily attached to the ultrasonic probe while the user instigates a calibration process, the results of which are stored in the calibration storage table 27.

Returning to Fig. 4, it is noted that the ultrasound system includes the secondary user input means (22) for controlling system operation. This user input means is preferably a scroll wheel with integrated button, and a separate button, implemented using either mechanical switches or any other technique well known and disclosed in the prior art. The ultrasound system decodes the user input 22 which is fed to the microcontroller (21). Any sort of modern microcontroller can be used, with the MSP430 series from Texas Instruments providing low standby power consumption, a variety of communications protocols, and non-volatile storage. The microcontroller communicates with the handheld display and processing system via interface 23 using a simple communications protocol, with I^2C being particularly well suited due to its multi-master capability.

Turning again to Fig. 5, there is illustrated the FPGA in more detail. The FPGA contains a timing generator (28) responsible for synchronising all aspects of the ultrasound transmission, reception, and processing. Memory for temporarily storing calibration data associated with the ultrasound transducer (31) and position and orientation measurement means (27) is provided in the FPGA. The ultrasound calibration data (31) can be used to normalise or equalise the received ultrasound data with respect to the transducer response by implementing a filter (25) before transmission to the handheld display and processing system. The position and orientation calibration data table (27) is used to normalise the measured position and orientation data and reduce nonlinearities in sensor performance resulting in a more accurate position and orientation measurement, using a pre-measured calibration data and appropriate environmental measurements such as temperature. The position and orientation data is combined with the ultrasound data in a first in first out (FIFO) memory (29), before encoding the data (30) into a communications protocol for serial transmission to the handheld display and processing system.

The incorporation of calibration means and processing of the calibration on the ultrasound system allows a standard interface to a host processor system wherein different transducer means can be physically exchanged without the need to alter or adjust the operation of the body of the equipment.

Various alternative embodiments of the Ultrasound system 2 are possible. Fig.6 illustrates a functional block diagram of one alternative embodiment. The alternative embodiment of the ultrasound system 2 contains an annular transducer 44 with multiple transmit and receive elements. The pulse generated by the transmit generator (32) can be delayed by a set of analog delay lines (33) to vary the transmit focal length of the ultrasound pulse. A diplexer (34) protects the receive circuits from high transmit voltages. The received signals from the transducer can be amplified (37), converted to digital data (38), and combined with the position and orientation measurements (40 and 41) by the FPGA (39) before transmission to the handheld display and processing unit. User input means (43) and a microcontroller 42 having non-volatile storage can also be provided.

Turning now to Fig. 7, there is illustrated a schematic part sectional view through the transducer system 2. The electronic and transducer portion are stored within the lower cavity 55. Attached to the lower cavity is an ultrasound gel storage and dispensing means. The ultrasound gel dispenser includes a cartridge of gel (53) connected to a disposable pump (49). The gel cartridge is protected by a cover (54) which can be removed or detachable. The gel can be stored in a flexible packaging reducing cost, with a solid plastic connection means (52). The pump consists of a storage well (45) with a flexible membrane mechanism (46). The storage well has an input channel (50) providing a path for the gel to move from the storage packaging (53) to the storage well (45) via an input valve (57). The storage well (45) is also connected to an output channel (48) via an output valve (58). A flexible button cover (51) is pressed by the user which in term depresses the flexible pump membrane (46), forcing gel stored in the storage well (45) out of the output channel (48) via the output valve (58) and eventually out the output nozzle (56). When the button is released, the membranes (46) elasticity returns it to its previous shape, sucking gel from the storage packaging (53) into the storage well (45) via the input valve (57) and input channel (50).

Turning now to Fig. 8 where there is illustrated a functional block diagram of the handheld display and processing system (3). The handheld display and processing system connects to the probe via a cable containing power, control communications, and data communications (56). The data input is connected to a FPGA (57), where the serial data is synchronised and decoded for reading by a microprocessor 58. The microprocessor is connected to volatile RAM storage (59) and non-volatile flash memory storage (60). The flash storage (60) contains program and operating system code, which is copied to and run from the volatile RAM storage (59). The display and processing system contains all or a subset of wired communications (67), audio input and output means (66), wireless communications means (65), peripheral storage means (64), user input means (63), display means (62), and processing means (58). The microprocessor can be programmed to process and interpret and display the ultrasound data in a variety of ways, including but not limited to A-mode imaging, B-mode imaging, M-mode imaging, Doppler audio with variable depth focus (gating), static colour Doppler, and Continuous wave Doppler. The preferred embodiment also provides a digital camera module (68), enabling users to record images of patients.

The wireless communications means can be used to save or download recorded patient data to an alternative system, such as but not limited to a medical records database operating on a personal computer, personal digital assistant (PDA), network server, or mainframe computer. The software on the system can include a client capable of connecting and synchronising to a medical records and practice management server, enabling a device registered to a physician to automatically download patient data from a practice management database to the device, removing the requirement for the physician to input patient data on the device. At the end of a patient session the device can upload data to a patient records database.

The handheld display and processing system provides an interface (56) with at least an always-on, single channel communications interface between the display and processing system and the ultrasonic probe. The interface is preferably a multi-master system, allowing either the display and processing system microprocessor or the ultrasound system microcontroller to wakeup the other system. The multi-master system allows either part of the system to initiate an ultrasound scan, providing maximum flexibility of operation.

The preferred embodiment's inclusion of a FPGA provides added flexibility in system expansion. The FPGA can be programmed to match the number of channels, communications speed, and even communications protocol of the probe. The FPGA can be programmed by the microprocessor (58) enabling future probes to provide updated FPGA firmware. Therefore, the system can be configured to match the operation of any probe design, even those invented in the future.

The handheld display and processing system provides non-volatile storage (64). An embodiment of the invention incorporates a secure data (SD) slot, enabling users to insert non-volatile flash memory cards. Another embodiment could incorporate a miniature hard disk. The user interface can be manipulated such that measurements taken by the device are recorded to non-volatile memory, along with a timestamp and other data identifying the patient.

It will be evident to the skilled hardware designer that the preferred embodiment can be implemented in many different forms depending on requirements. The forms can include standard microcontroller and DSP / FPGA components to a full custom ASIC design. Hence, the system could be constructed of numerous separate components (such as op-amps, A/D converters, D/A converters, digital signal processors, memory, displays, communications components etc), or could be comprised primarily of a mixed-mode application specific integrated circuit (ASIC) with a small number of support components.

The forgoing describes preferred forms of the present invention only. Modifications, obvious to those skilled in the art can be made thereto without departing from the scope of the invention.

Further, although the preferred embodiments are largely described in terms of medical/veterinary applications, the invention also finds use in other industrial applications, such as inspection of materials for internal damage/imperfections and such uses are encompassed within the scope of the present invention.

We claim:

1. An ultrasound measurement system including:

a handheld display and processing means;

an ultrasound transducer and processing means of a substantially similar weight to the handheld display and processing means;

a transmission cable interconnecting the handheld display and processing means with the ultrasound transducer and processing means and being of sufficient length to provide a means to mechanically locate the system around the neck of a user.

2. A system as claimed in claim 1 wherein the handheld display and processing means includes a primary user input means and the ultrasound transducer and processing means includes a secondary user input means.

3. A system as claimed in claim 2 wherein the primary user input means consists at least of a scroll wheel and push activated buttons, and the secondary user input means consists of a scroll wheel and push activated buttons.

4. A system as claimed in any previous claim wherein the ultrasonic transducer means further includes;

an ultrasonic transmit and receive means, and a position and orientation measuring means in order that the received ultrasound signals can be displayed in spatial register with each other.

5. A system as claimed in claim 4 wherein said ultrasound transducer means further includes a non-volatile memory for storing position and orientation calibration data.

6. A system as claimed in claim 5 wherein the ultrasound transducer means consists of a means for processing the position and orientation data and the calibration data and producing normalized position and orientation data.

7. A system as claimed in claim 1 wherein the display and processing means comprises a microphone and software means for recording user voice (dictation).

8. A system as claimed in claim 1 wherein the display and processing means incorporates communications means for connecting and sending recorded data to/from other systems for importing or exporting patient data.

9. A system as claimed in claim 1 wherein the display and processing means includes an integrated camera for recording images.

10. A system as claimed in claim 1 wherein the ultrasound transducer and processing means includes a gel dispensing means with a replaceable gel cartridge.

11. A system as claimed in claim 1 wherein the ultrasound transducer and processing means provides a calibration storage means and a processing means for generating normalized ultrasound data.

12. A system as claimed in claim 2 wherein the position and orientation means include output signals that are processed to generate user input mouse positions when not actively performing ultrasound input.

13. A system as claimed in claim 1 wherein the handheld processing and display unit furthering includes a strap fitting enabling the unit to be attached to a users arm.

14. An ultrasonic measurement and imaging system comprising:

ultrasonic transducer means consisting of one or more sensors for the transmission and reception of ultrasonic signals;

ultrasonic processing means comprising a transmitting section which generates one or more ultrasonic signals which stimulate the ultrasonic transducer means to transmit ultrasound into the body of the patient and a receiving section which receives ultrasonic signals returned from the patient's body via a combination of reflection and refraction;

transmitter control means which controls the form, frequency and timing of the ultrasound waves transmitted by the ultrasonic transducer means as determined by inputs from one or more of a user interface means, parameters stored in a calibration storage means and the ultrasound signal received back by the ultrasonic processing means;

receive control means which controls the way in which the ultrasound signal received back from the patient via the receive section of the ultrasonic transducer means is processed;

orientation measurement means which enables the measurement of the position and direction in space of the transmitted or received ultrasound beam or beams, the output of the orientation measurement means being made available to the receive control means in order that the received ultrasound signals can be stored and subsequently displayed in spatial register with each other;

signal storage means which stores the processed output of the receive control means along with associated parameters from the orientation measurement means;

display means which provides graphical and numerical outputs for viewing by the equipment user.

15. A system as claimed in claim 14wherein the output of the display means includes at least one of: A-mode imaging, B-mode imaging, M-mode imaging, doppler audio with variable depth focus (gating), Static colour Doppler or Continuous wave Doppler.

16. A system as claimed in any previous claim 14, 15 further comprising: remote communication means which transmits the contents of the signal storage means or display means to a remote display or recorder.

17. A system as claimed in claim 16 wherein said remote communications means further includes a remote system control means for controlling the operation of the system.

18. A system as claimed in any previous claim 14 – 17 further comprising a calibration storage means which updates and stores calibration data for the ultrasonic transducer means.

19. A system as claimed in any previous claim 14 – 18 further comprising a user interface means by which the user can select different functional options for the equipment, start and stop ultrasound data collection, examine the content of the calibration storage means, instigate remote communications with other devices, and enter patient information.

20. A system as claimed in any previous claim 14 – 19 further including a physical interconnection means which performs the dual function of optionally, communicating the signals between the ultrasonic transducer module and the rest of the system and providing a means to mechanically locate the system on the neck of the user in a manner analogous to that of a conventional stethoscope.

21. A system as claimed in any previous claim 14 – 20 further including a coupling media storage and dispensing means accommodating a replaceable coupling media gel cartridge and dispensing mechanism.

22. A handheld Data Processing Unit (DPU) for interfacing to a number of possible ultrasonic transducer means, the unit including:

a user interface means for input by a user of feedback information;

a processing unit for controlling input, output;

a digital signal processing unit for performing analysis and processing of captured data;

remote communication means for connecting with external devices;

storage interfaces for providing non-volatile data storage;

a display means;

a probe interface for attaching one of said ultrasonic transducer means.

23. A unit as claimed in claim 22 further comprising a calibration storage means provided for the storage of calibration data on a probe enabling a consistent interface format regardless of probe design and construction.

24. A calibration storage means as claimed in claim 23 utilised in conjunction with a field-calibration process wherein a standard mass is temporarily attached to the ultrasonic probe while the user instigates a calibration process, the results of which are stored in the calibration storage means.

25. A system as claimed in claim 14 further comprising a user input means which provides for a mode-switch of the probe to a mouse function when instructed.

26. A system as claimed in claim 14 further comprising a user input means provides for the inclusion of a scroll wheel on the probe to provide convenient control.

27. A system as claimed in claim 26 wherein, when in an operational mode, the scroll wheel can easily adjust the depth of focus of the ultrasound beam.

28. A system as claimed in claim 14 further comprising an ultrasonic probe and an acoustic probe, providing the user with the option to use multiple functions without having to change the probe.

29. An ultrasound system substantially as hereinbefore described with reference to the accompanying drawings.

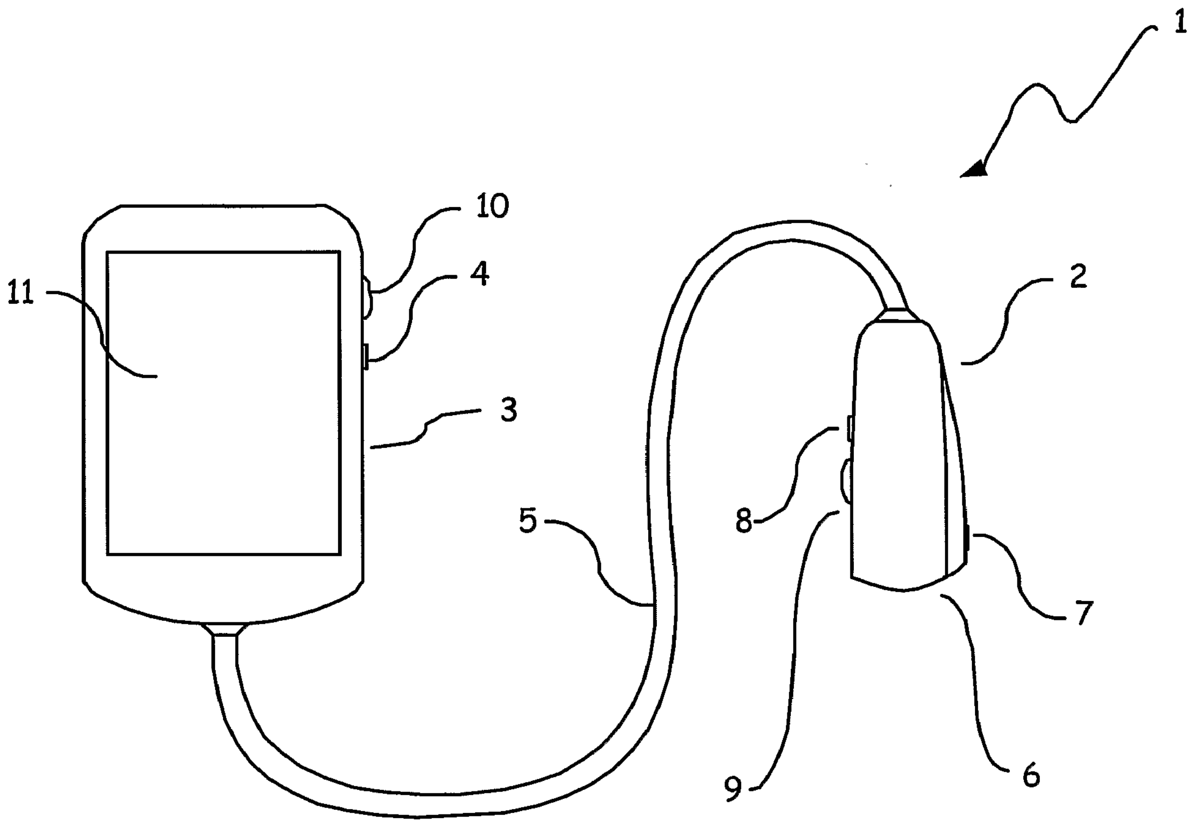


Fig. 1

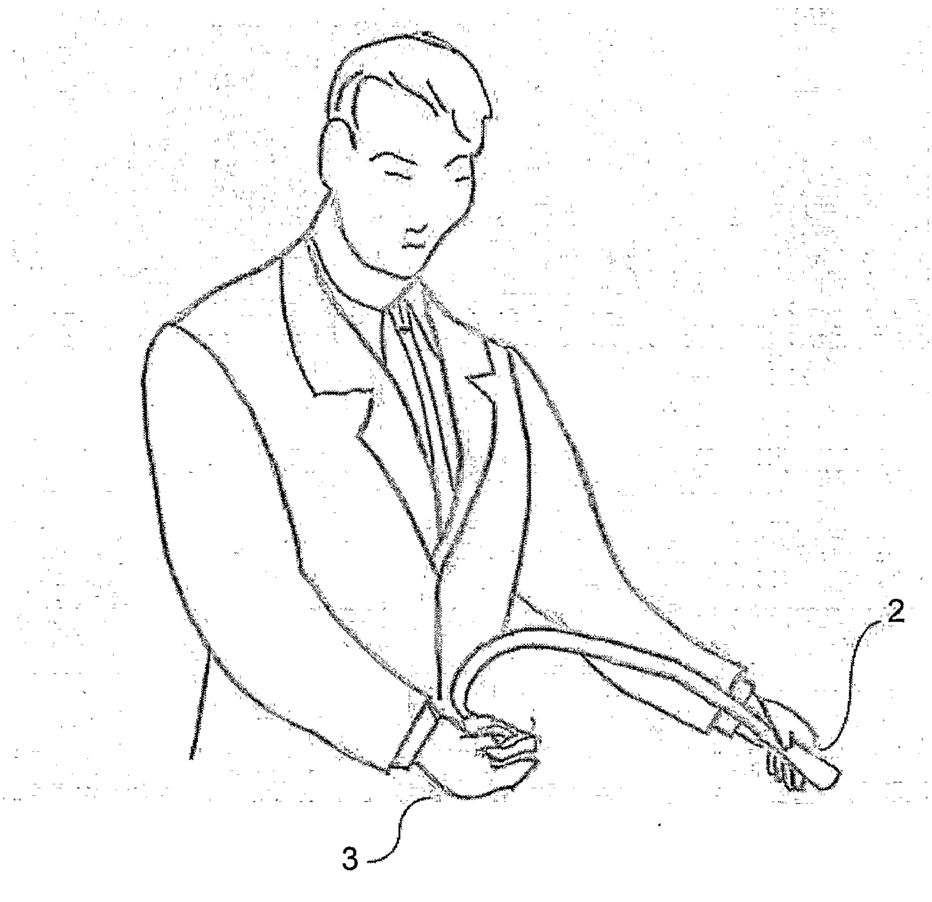


Fig. 2

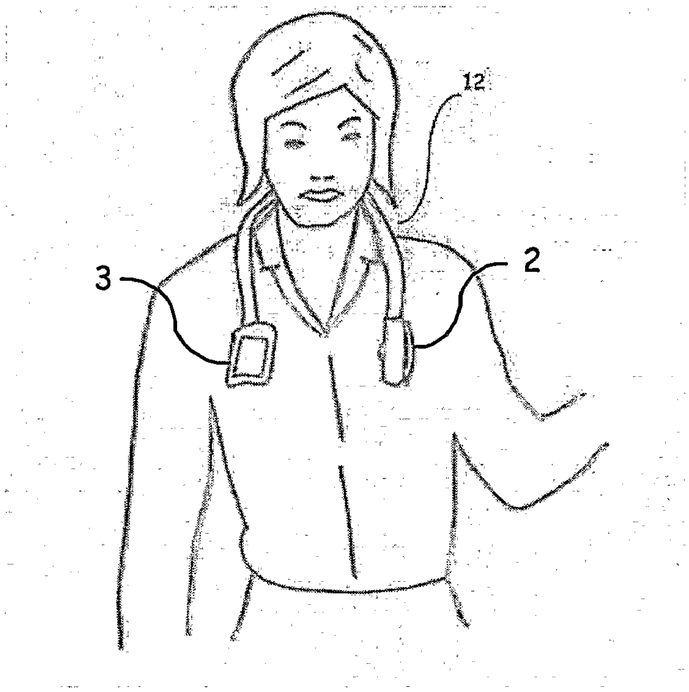
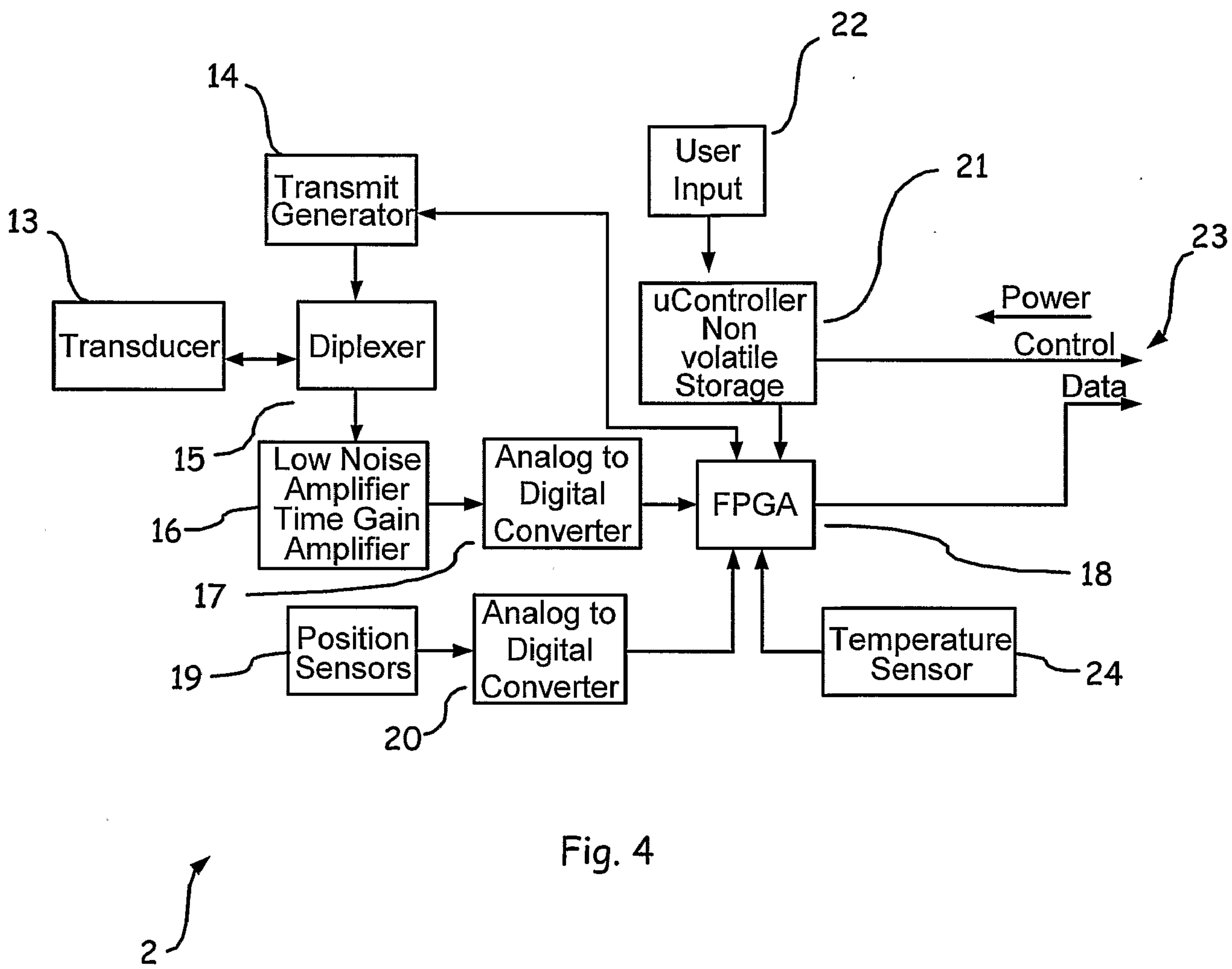


Fig. 3



22
14
User Input
21
Transmit Generator
13
23
uController Non volatile Storage
Power
Transducer
Diplexer
Control
Data
15
Low Noise Amplifier Time Gain Amplifier
Analog to Digital Converter
FPGA
16
17
18
Position Sensors
Analog to Digital Converter
Temperature Sensor
19
24
20
2

Fig. 4

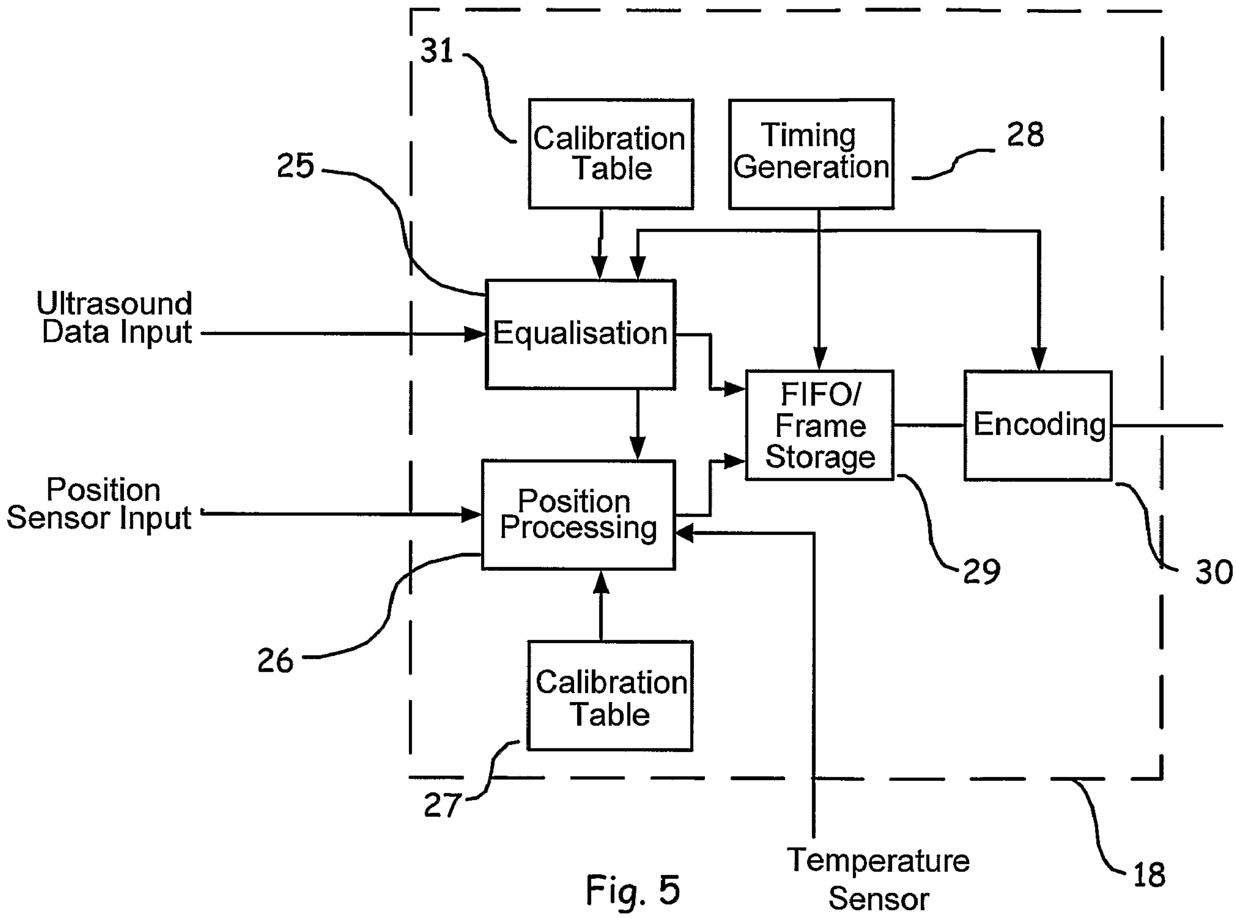
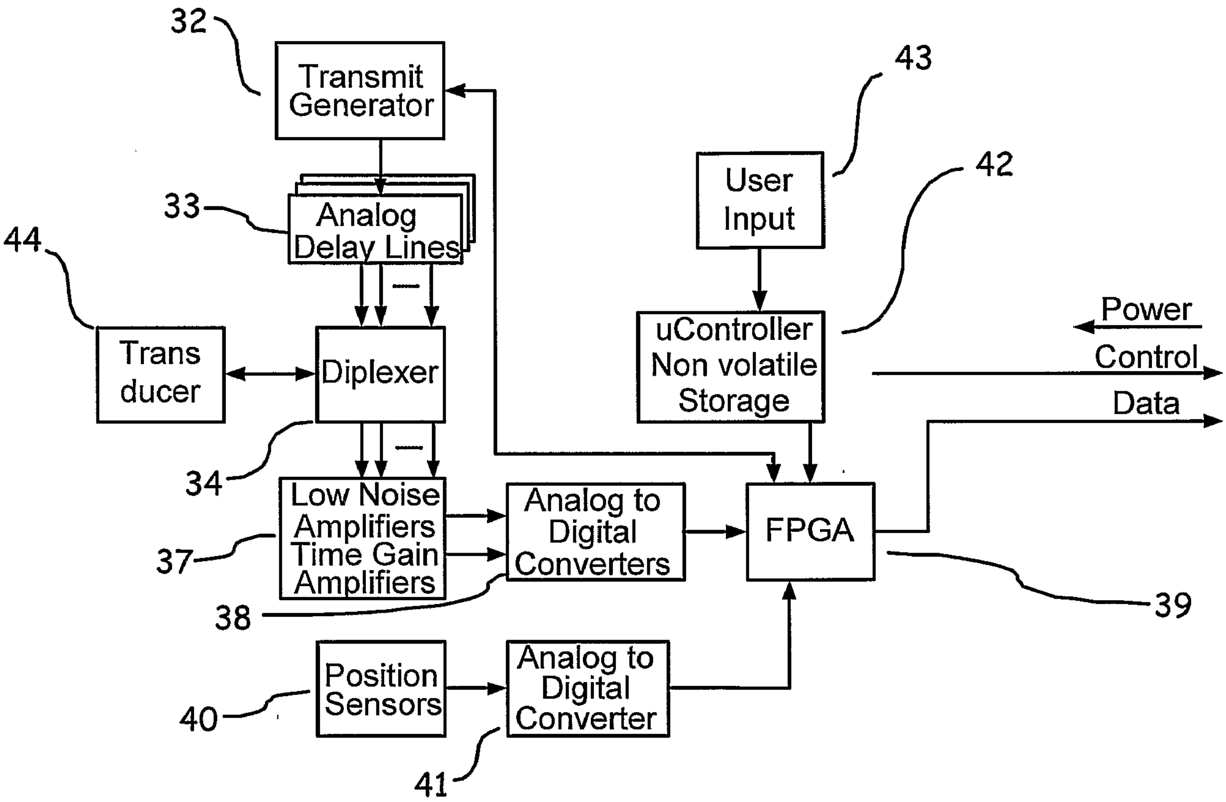

31
Calibration Table
Timing Generation
28
25
Ultrasound Data Input
Equalisation
FIFO/ Frame Storage
Encoding
Position Sensor Input
Position Processing
29
30
26
Calibration Table
27
Temperature Sensor
18

Fig. 5



32
Transmit Generator
33
Analog Delay Lines
44
Trans ducer
Diplexer
34
Low Noise Amplifiers Time Gain Amplifiers
37
38
Analog to Digital Converters
User Input
43
uController Non volatile Storage
42
Power
Control
Data
FPGA
39
Position Sensors
40
Analog to Digital Converter
41

Fig. 6

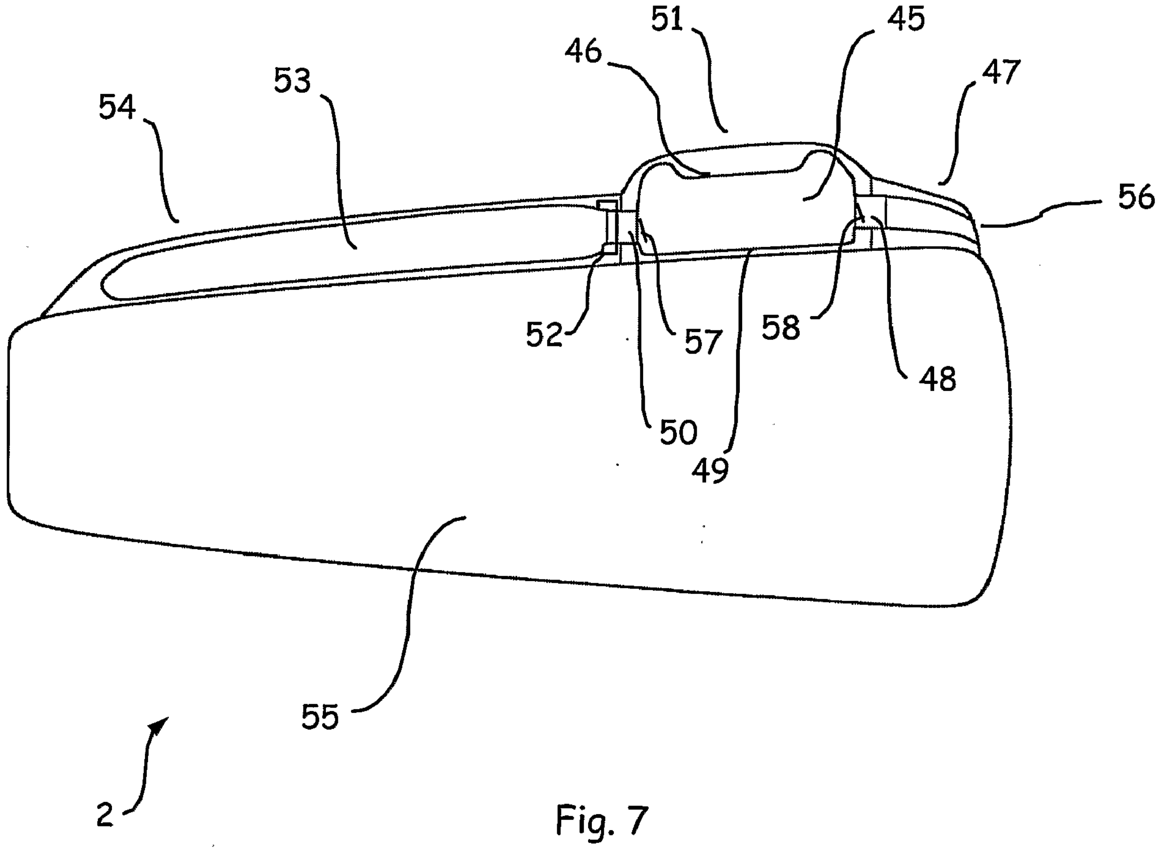
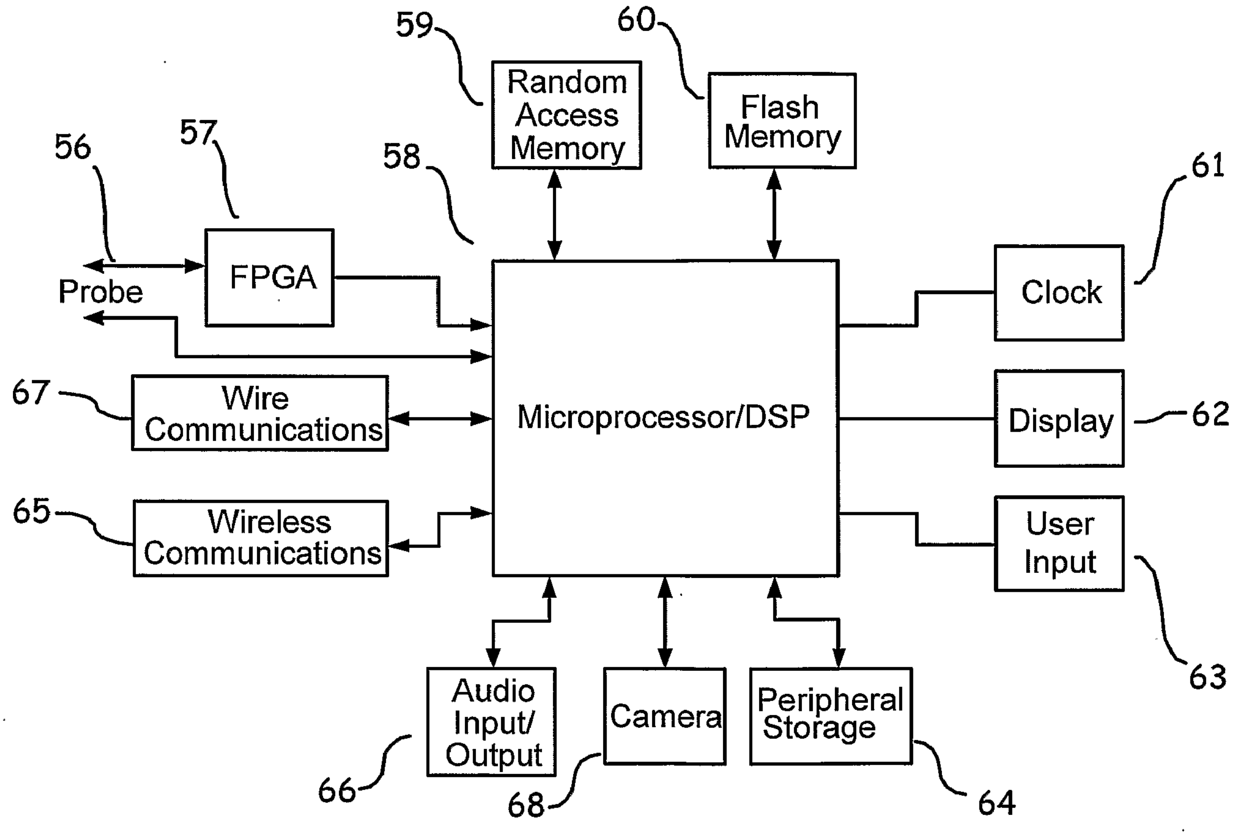


Fig. 7



59
Random Access Memory
60
Flash Memory
56
57
58
61
FPGA
Probe
Clock
Microprocessor/DSP
67
Wire Communications
Display
62
65
Wireless Communications
User Input
63
Audio Input/ Output
Camera
Peripheral Storage
66
68
64

Fig. 8


3

INTERNATIONAL SEARCH REPORT	International application No. **PCT**/AU2006/001658

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. *A61B 8/00* (2006.01)

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)

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 practicable, search terms used)
DWPI -IPC A61B/IC, G01S/IC; & keywords (ultrasound, ultrason+, hand, held, portable, grip+, personal, miniature, display, lcd, tft, monitor, screen, process+, comput+, transduc+, sensor, probe, cabl+, wire, wiring, neck, hang, wrap)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/0139671 A1 (WALSTON et al.) 24 July 2003 See in particular paragraph [0047] and figure 7.	1 to 13
X	US 6,126,608 A (KEMME et al.) 3 October 2000 See in particular figures 1 and 6.	1 to 13
X	JP 2003-299647 A (GE MED SYS GLOBAL TECH CO LLC) 21 October 2003 See in particular figure 5.	1 to 13

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

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

"E" earlier application or patent 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 when the document is taken alone

"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

Date of the actual completion of the international search	Date of mailing of the international search report
12 December 2006	29 JAN 2007
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer **Peter West** Telephone No : (02) 6283 2108

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/001658

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 20004872 U1 (WEYLANDT) 16 March 2000 See in particular figure 1.	1 to 13

INTERNATIONAL SEARCH REPORT	International application No. PCT/AU2006/001658

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

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

1. ☐ Claims Nos.:
   because they relate to subject matter not required to be searched by this Authority, namely:

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

3. ☐ Claims Nos.:
   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

[See Supplemental Box]

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
   1 to 13

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT	International application No. **PCT**/AU2006/001658

Supplemental Box
(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No:

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

This International Searching Authority has found that there are different inventions as follows:

- Claims 1 to 13 are directed to an ultrasound measurement system. It is considered that the transmission cable interconnecting the handheld display and processing means with the ultrasound transducer and processing means comprises a first distinguishing feature.
- Claims 14 to 21 are directed to an ultrasonic measurement and imaging system comprising an ultrasonic transducer and processing means. It is considered that the orientation measurement means comprises a second distinguishing feature.
- Claims 22 to 29 are directed to a handheld Data Processing unit comprising communications and digital signal processing means. It is considered that the probe interface comprises a third distinguishing feature.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

The only feature common to all of the claims is a display means. However this common feature is generic in the art. This means that the common feature can not constitute a special technical feature within the meaning of PCT Rule 13.2, second sentence, since it makes no contribution over the prior art.

Because the common feature does not satisfy the requirement for being a special technical feature it follows that it cannot provide the necessary technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a posteriori*.

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member			
US	2003139671	US	6780154	US	2003139664
US	6126608	AU	56766/00	WO	0070366
JP	2003299647				
DE	20004872				

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX

专利名称(译)	超声测量系统和方法		
公开(公告)号	[EP1959836A4](#)	公开(公告)日	2010-11-17
申请号	EP2006804480	申请日	2006-11-07
申请(专利权)人(译)	signostics有限公司		
当前申请(专利权)人(译)	signostics有限公司		
[标]发明人	BARTLETT STEWART GAVIN COSTELLO ROGER MICHAEL		
发明人	BARTLETT, STEWART, GAVIN COSTELLO, ROGER, MICHAEL		
IPC分类号	A61B8/00		
CPC分类号	A61B8/4281 A61B8/4427 A61B8/4455 A61B8/462 A61B8/56 A61B2560/0431 G01S7/003 G01S15/8906		
代理机构(译)	贝雷斯福德KEITH DENIS LEWIS		
优先权	2005906152 2005-11-07 AU		
其他公开文献	EP1959836A1		
外部链接	[Espacenet](#)		

摘要(译)

一种超声测量系统，包括手持显示器和处理装置，超声换能器，与手持显示器和处理装置具有基本相似重量的处理装置，以及将手持显示器和处理装置与超声换能器和处理装置互连的传输电缆该电缆具有足够的长度以提供将系统机械地定位在使用者颈部周围的装置。