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(71) Applicant *(for all designated States except US)*: **USCOM LIMITED** [AU/AU]; 323 Old Coast Road, Korora, NSW 2450 (AU).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BUTLER, Paul** [AU/AU]; USCOM Pty Ltd, P O Box J241, Coffs Harbour, NSW 2450 (AU). **PHILLIPS, Robert, Allan** [AU/AU]; P O Box J241, Coffs Harbour, NSW 2450 (AU). **DAVEY, Gary** [AU/AU]; USCOM Pty Ltd, P O Box J241, Coffs Harbour, NSW 2450 (AU).

(74) Agent: **SHELSTON IP**; 60 Margaret Street, Sydney NSW 2000 (AU).

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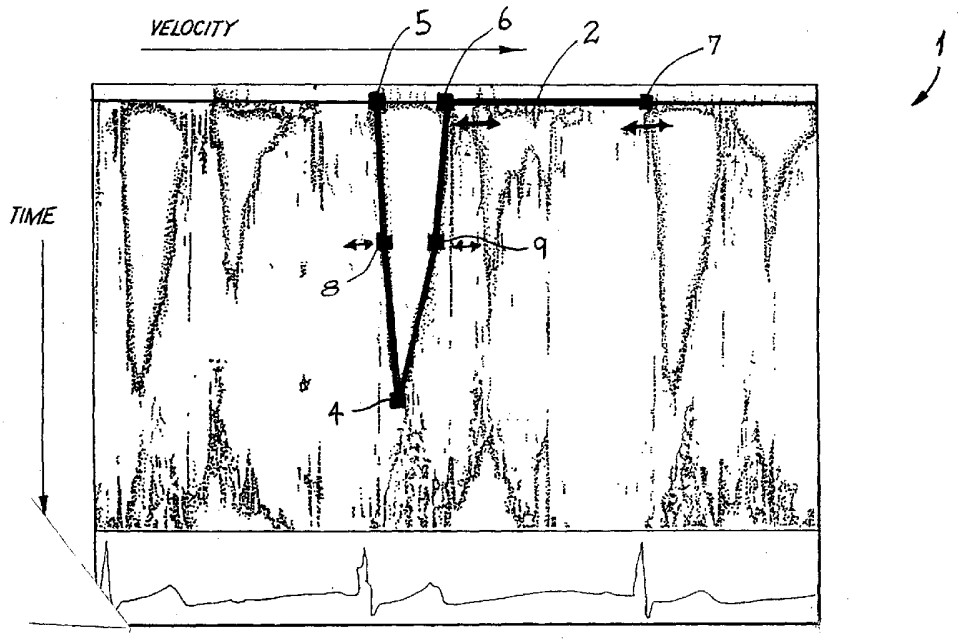
[Continued on next page]

(54) Title: DERIVING PARAMETER INFORMATION FROM BLOOD FLOW SIGNAL



(57) Abstract: A method for measuring parameters in a Doppler Flow Profile utilising a computer display device, the method comprising the steps of: (a) displaying a background image of the Doppler flow profile on the display device; (b) displaying a series of interactive graphical objects over the background image, the elements having adjustable position parameters; (c) providing an interactive capability for a user to adjust the position of portions of the graphical elements; (d) calculating the parameters from the relative position of the portions of the graphical elements.

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Declaration under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

DERIVING PARAMETER INFORMATION FROM BLOOD FLOW SIGNAL

Field of the Invention

The present invention relates to the field of signal monitoring and, in particular, discloses a method and apparatus for deriving parameter information from a signal.

Background of the Invention

Blood flow within the human body is cyclic and is responsive to the changing pressures generated by contraction and relaxation of the heart muscles. This cyclic contraction and relaxation produces pulsating blood flow. Known Doppler ultrasound techniques can measure the phase shift associated with this flow and display the signal on a screen. An example of such a system is provided in Patent Cooperation Treaty Publication Number WO 99/66835 entitled "Ultrasonic Cardiac Output Monitor", the publication of which is incorporated herein by cross-reference.

The Doppler Ultrasound flow profiles provide important clinical information. An example of a time v. velocity flow profile is shown in Fig. 1 for a measurement taken utilising the technique of the aforementioned PCT Publication. Unfortunately, it is often the case that any derived parameters are currently measured using a manual trace method so as to provide multiple haemodynamic parameters reflecting the underlying flow characteristics. This measurement can be time consuming and depends for accuracy upon the mechanical co-ordination of the operator.

Cardiac contraction and relaxation varies both in rate and force from beat to beat, so a comprehensive understanding of the function may require multiple sequential or serial measurements.

Fully automated edge detection methods have been used with limited success in peripheral vessel and simple flow applications, however intracardiac flow is

characterised by artefacts which are random and cannot be easily described using fully automated methods. Automated methods are generally not positively accepted in clinical practice because of the inherent error and insensitivity.

Summary of the Invention

It is an object of the present invention to provide an alternative form of deriving parameters from a signal output device.

In accordance with a first aspect of the present invention, there is provided a method for measuring parameters in a Doppler Flow Profile utilising a computer display device, the method comprising the steps of: (a) displaying a background image of the Doppler flow profile on the display device; (b) displaying a series of interactive graphical objects over the background image, the elements having adjustable position parameters; (c) providing an interactive capability for a user to adjust the position of portions of the graphical elements; (d) calculating the parameters from the relative position of the portions of the graphical elements.

The interactive graphical objects can include a first object substantially intersecting the apex of a series of adjacent Doppler flow profiles. At least one of the interactive graphical objects preferably can include a substantially triangular shape sized substantially to fit around an initial portion of a flow cycle. The apex of the triangular shape can be located substantially at the peak flow velocity of the background image. At least one of the interactive graphical objects further preferably can include a segment from a base of the triangular shape to an adjacent initial portion of a flow cycle. The triangular shape preferably can include a series of manipulation points along at least one side thereof.

Brief Description of the Drawings

Preferred embodiments of the present invention will now be described by way of example only with reference to the accompanying drawings in which:

Fig. 1 illustrates an example Doppler Flow Profile;

Fig. 2 illustrates the utilisation of template structures in conjunction with a Doppler flow profile; and

Fig. 3 illustrates one example computer architecture on which the preferred embodiment can be carried out.

Description of the Preferred and Other Embodiments

The preferred embodiment provides a semi-automated digital method for measuring Doppler flow profiles which is quicker and often more accurate than the current manual methods.

Turning to Fig. 2, the preferred embodiment provides for the overlay of various template structures on a standard received flow profile e.g. 1. The profile 1 can be a screen snapshot taken from a Doppler flow measurement unit. As shown in Fig. 2, on top of the profile 1, a simple flow template is presented having interconnected structural elements 2,3. The elements 2,3 being shown for the characterising of a normal flow profile, being a simple systolic ejection cycle for transpulmonary and transaortic flow.

When alternative flows are visualised, other templates can be provided. For example, a biphasic pattern is selected for transmitral flow and a monophasic pattern for transmitral flow in atrial fibrillation. A user interface and template can be provided for selecting the appropriate profile.

The template components 3 are initially interconnected at an intersection 4 representing the peak flow velocity. The point 4 is adjustable by the user in the vertical direction.

The component 2 forms an adjustable base line and is constrained to be always horizontal. The template also includes adjustable points 5,6,7,8, 9. The points 5,6,7 are movable along the base line 2. The points 8,9 are moveable in a horizontal manner and control attached line segments.

At each point 4-9 there is a digital handle which can be moved by mouse in the instance of conventional digital display, or by stylus if the application is for touch screen display, to allow for exact superimposition of the template point over the underlying flow profile.

From the positioning of the template points, a number of conventional haemodynamic parameters such as peak flow velocity, mean flow velocity, peak flow velocity, mean pressure gradient, velocity time integral, ejection time and heart rate can be calculated. The input of other clinical variables by a user allows for derivation of other clinically useful haemodynamic variables such as stroke volume and cardiac output.

Once the template is adjusted to superimpose the underlying flow profile, the template can remain on the screen as the Doppler flow signal is re-activated, allowing for a simple visual comparison of the real time signal with the prior measurements. When further measurements are required the streaming Doppler signal can be frozen, and the entire template moved in a single action to superimpose the new flow profile for measurement. Minor adjustments using the digital handles ensures accurate

superimposition of the new flow profile and a new set of variables can be derived. The minor adjustments can thereby result in a recalculation of the template points.

This touchpoint method of tracing simple geometric screen elements, allows for rapid, and reproducible measurement of important cardiac haemodynamic Doppler flow profiles.

The method can also be utilised in any screen measurement of a simple geometric signal, which will include Doppler flow profiles from other vessels in the body. This method is able to improve the currently practiced direct trace of these profiles which is both time consuming and dependent on the co-ordination skills of the operator. The application of this method has significant time and cost effectiveness consequences in a variety of applications where rapid and accurate tracing of displayed signals is required.

The preferred embodiment can be implemented by suitable programming of an interactive graphics package by the skilled graphics programmer. The implementation can be formulated, for example, in Visual C++, TCL/TK etc.

The preferred embodiment is preferably implemented on a standard workstation type computer arrangement utilising standard computer graphics programming languages. A suitable hardware arrangement for programming can be as shown in Fig. 3 with central processing unit 41, memory 42, Disk store 43 and IO Device Controller 44 arranged around a central bus 45. The arrangement 40 can be suitably programmed in the usual manner to carry out the operations of the preferred embodiment.

Whilst each point can be fully moveable, preferably when first used, various defaults are provided. For example, the points 8 and 9 shall always have their Y coordinate half way between the points 5 and 4. The points 5, 6, 7 shall always have their Y coordinate equal to the 0 level on the scale.

The default sizes can be as set out in the following table:

Point	X	Y
5	0	0
8	15% 5 to 6	50% 5 to 4
4	50% 5 to 6	5 to 4
9	85% 5 to 6	50% 5 to 4
6	5 to 6	0
7	5 to 7	0

Table 2 Default Touchpoint

Where

- 5 to 6 distance = 0.4 seconds
- 5 to 4 distance = 220/256 of the 0 to lower scale distance
- 6 to 7 distance = 0.9 seconds – 5 to 6 distance

The user moves the 6 points of the template to encompass the flow pattern on the flow display. All points shall be able to be dragged to a valid location. The valid locations for points are

- Point 5 must be to the left or equal to 8
- Point 8 must be between points 5 and 4
- Point 4 must be between points 8 and 9
- Point 9 must be between points 4 and 6
- Point 6 must be between points 9 and 7
- Point 7 must be to the left of point 5

This shall be achieved by moving the 6 points as follows

- Touching to the right of midway between points 5 and 7 shall move the 7 point in a Y direction to the position of the touch

- Touching to the left of midway between points 6 and 7 or to the right of midway between points 6 and 9 shall move the 6 point in a Y direction to the position of the touch.
- Touching to the left of midway between points 9 and 6 or to the right if midway between points 9 and 4 shall move the 9 point in a Y direction to the position of the touch.
- Touching below the midway between point 8/9 and 4 will move point 4 to the position of the touch. The 4 point can be moved in an X and Y direction. When the Y location of the 4 point is moved the Y position of the 8 and 9 points shall be re-located to be halfway in the Y plane between points 5 and 4
- Touching to the left of midway between points 8 and 5 or to the right of midway between points 8 and 4 shall move the 8 point in a Y direction to the position of the touch.
- Touching to the right of midway between points 5 and 8 shall move the 5 point in a Y direction to the position of the touch.

The following measures shall be calculated from the Touchpoint

Measure	Units	Abbrevation
Peak Velocity	m/s	Vpk
Mean Pressure Gradient	mmHg	Pmn
Velocity-Time Integral	cm	vti
Heart Rate	bmp	HR
Minute Distance	m/min	MD
Ejection Time Ratio	%	ET%
Stroke Volume	cm^3	SV
Cardiac Output	1/min	CO
Cardiac Index	$1/min/m^2$	CI

Table 3 Measures

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

We claim:

1. A method for measuring parameters in a Doppler Flow Profile utilising a computer display device, the method comprising the steps of:

(a) displaying a background image of the Doppler flow profile on the display device;

(b) displaying a series of interactive graphical objects over the background image, said elements having adjustable position parameters;

(c) providing an interactive capability for a user to adjust the position of portions of said graphical elements;

(d) calculating the parameters from the relative position of said portions of said graphical elements.

2. A method as claimed in claim 1 wherein said interactive graphical objects include a first object substantially intersecting the apex of a series of adjacent Doppler flow profiles.

3. A method as claimed in any previous claim wherein at least one of said interactive graphical objects includes a substantially triangular shape sized substantially to fit around an initial portion of a flow cycle.

4. A method as claimed in claim 3 wherein the apex of said triangular shape is located substantially at the peak flow velocity of the background image.

5. A method as claimed in claim 3 wherein said at least one of said interactive graphical objects further includes a segment from a base of said triangular shape to an adjacent initial portion of a flow cycle.

6. A method as claimed in claim 3 wherein said triangular shape includes a series of manipulation points along at least one side thereof.

7. A method substantially as hereinbefore described with reference to the accompanying drawings.

8. A computer system when implementing the method of any of claims 1 to 7.

Fig. 1

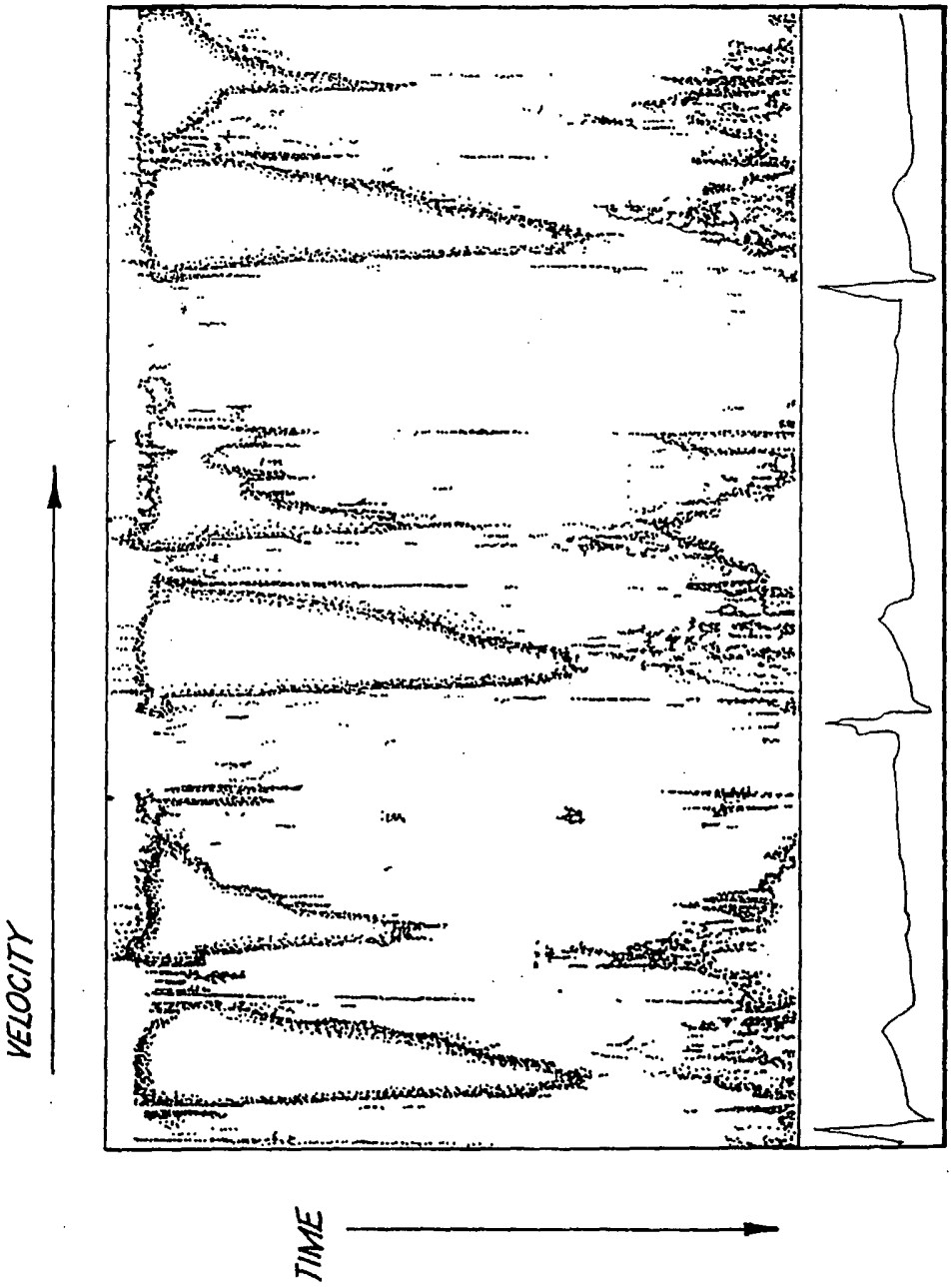
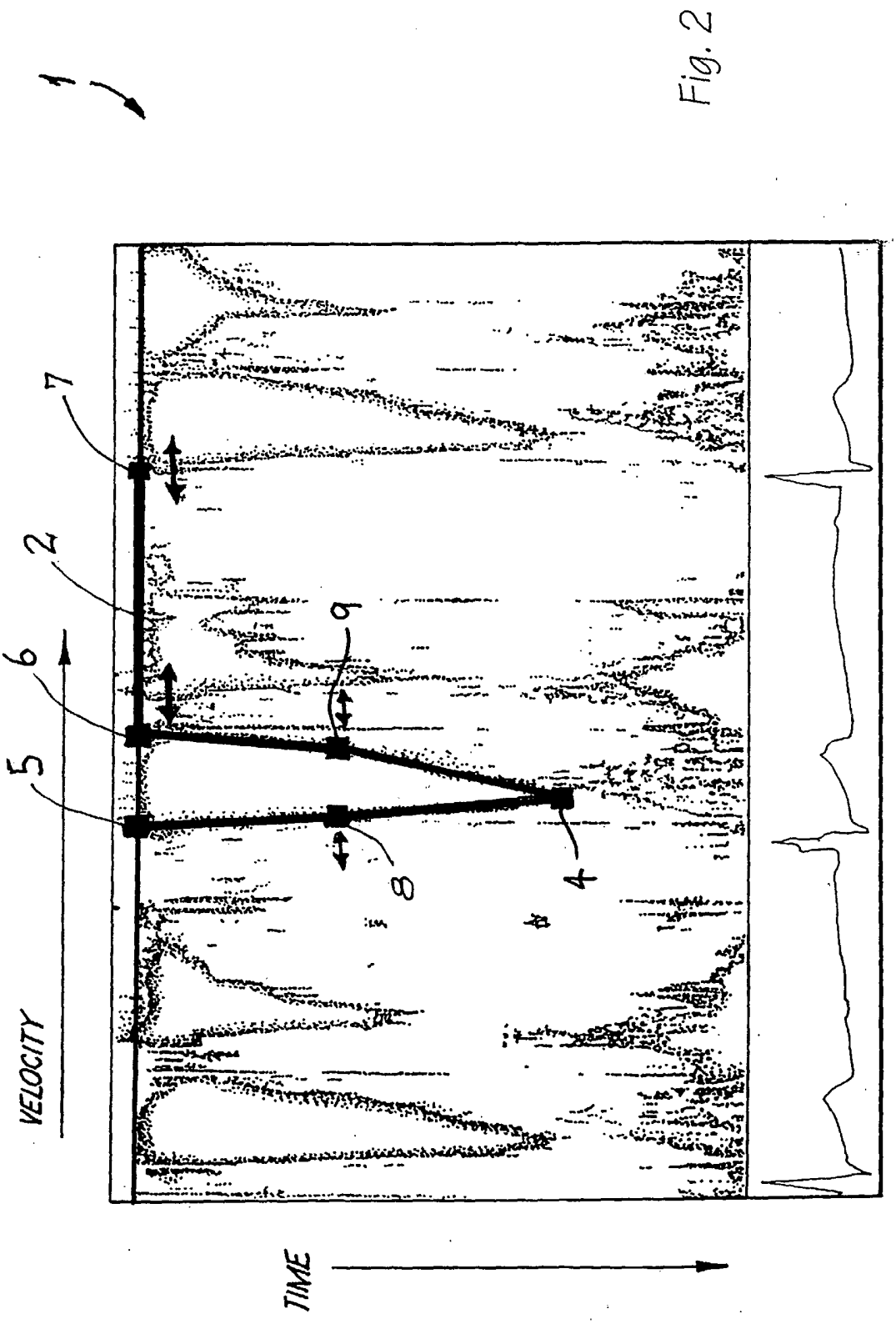


Fig. 2



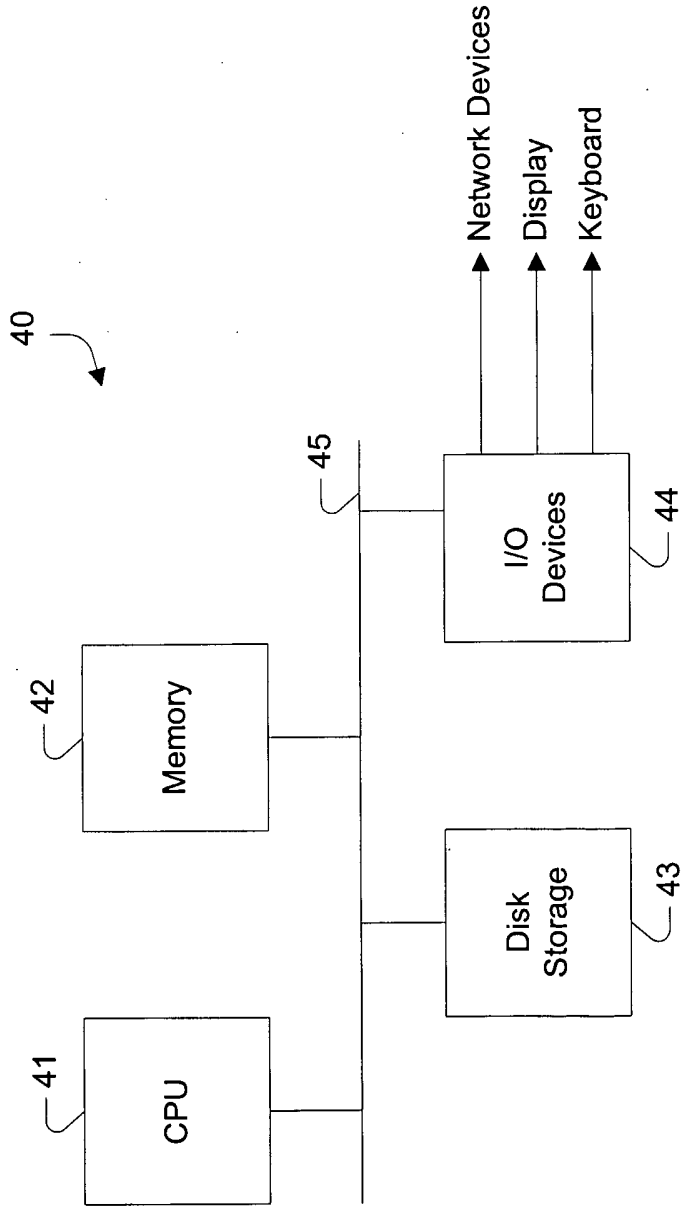

40
41
CPU
42
Memory
43
Disk Storage
44
I/O Devices
45
Network Devices
Display
Keyboard

Fig. 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2004/000343

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61B 8/06, G01S 15/88, G01S 13/00

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)
SEE ELECTRONIC DATABASES CONSULTED

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)
MEDLINE, USPTO, DWPI: blood, ultrasonic, ultrasound, acoustic, doppler, flow, velocity, speed, graph, screen, diagram, represent, image, plot, profile, display, overlap, overlie, template, impose, point, guid, scale, adjust, alter, chang, interact, modify, A61 5/00, A61B 8/00, G01N 29/00, G01F/00.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	NUDELMAN, S.; MANSON, A.L.; HALL, A.F.; KOVACS, S.J. Comparison of Diastolic Filling Models and Their Fit to Transmitral Doppler Contours. Ultrasound in Med. & Biol., Vol. 21, (8), pages 989-999, 1995 Abstract, Fig. 1-6.	1-8
A	TONTI, G.; RICCARDI, G.; DENARO, F.M.; TRAMBAIOLO, P.; SALUSTRI, A. From Digital Image Processing of Colour Doppler M-Mode Maps to Noninvasive Evaluation of The Left Ventricular Diastolic Function: A Dedicated Software Package Ultrasound in Med. & Biol., Vol.26, (4), pages 603-611, 2000 Whole document.	1-8

[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

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"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
2 June 2004

Date of mailing of the international search report
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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

MATTHEW FORWARD
Telephone No : (02) 6283 2606

INTERNATIONAL SEARCH REPORT

International application No.
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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,A	WO 2003060553-A2 (KONINK PHILIPS ELECTRONICS NV) 24 July 2003 Whole document	1-8
P,A	US 2003114756-A1 (LI) 19 June 2003 Whole document	1-8

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU2004/000343

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	2003114756	JP	2003220060
WO	03060553	NO	FAMILY

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

END OF ANNEX