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Cheng

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(54) **METHOD AND DEVICE FOR MEASURING PARAMETERS OF CARDIAC FUNCTION**

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Related U.S. Application Data

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(51) **Int. Cl.**
A61B 5/00 (2006.01)

(52) **U.S. Cl.** **600/324**

(58) **Field of Classification Search** 600/324
See application file for complete search history.

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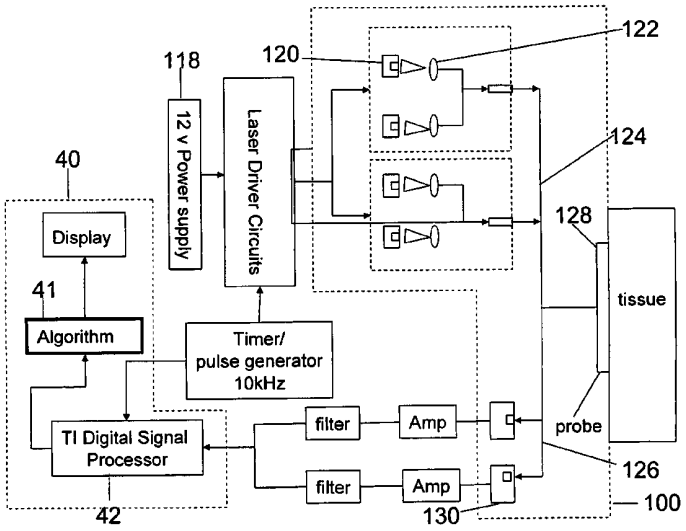
Primary Examiner — Clayton E LaBalle
Assistant Examiner — Noam Reisner

(57) **ABSTRACT**

A device for non-invasively measuring at least one parameter of a cardiac blood vessel in a patient is provided. The device comprises at least one light source that emits light in the 400 nm to 1000 nm wavelength range; at least one photodetector adapted to receive light emitted by the light source and generate an output based on the received light, wherein said light is reflected from or transmitted through tissue of the patient, the output of said photodetector being correlated with a parameter of the blood vessel; and at least one probe for facilitating delivery of light from the light source to an external tissue site on the patient in the proximity of the cardiac blood vessel and receipt of light by the photodetector. A system and methods of monitoring/measuring cardiac parameters utilizing the device and/or system are also provided.

7 Claims, 18 Drawing Sheets



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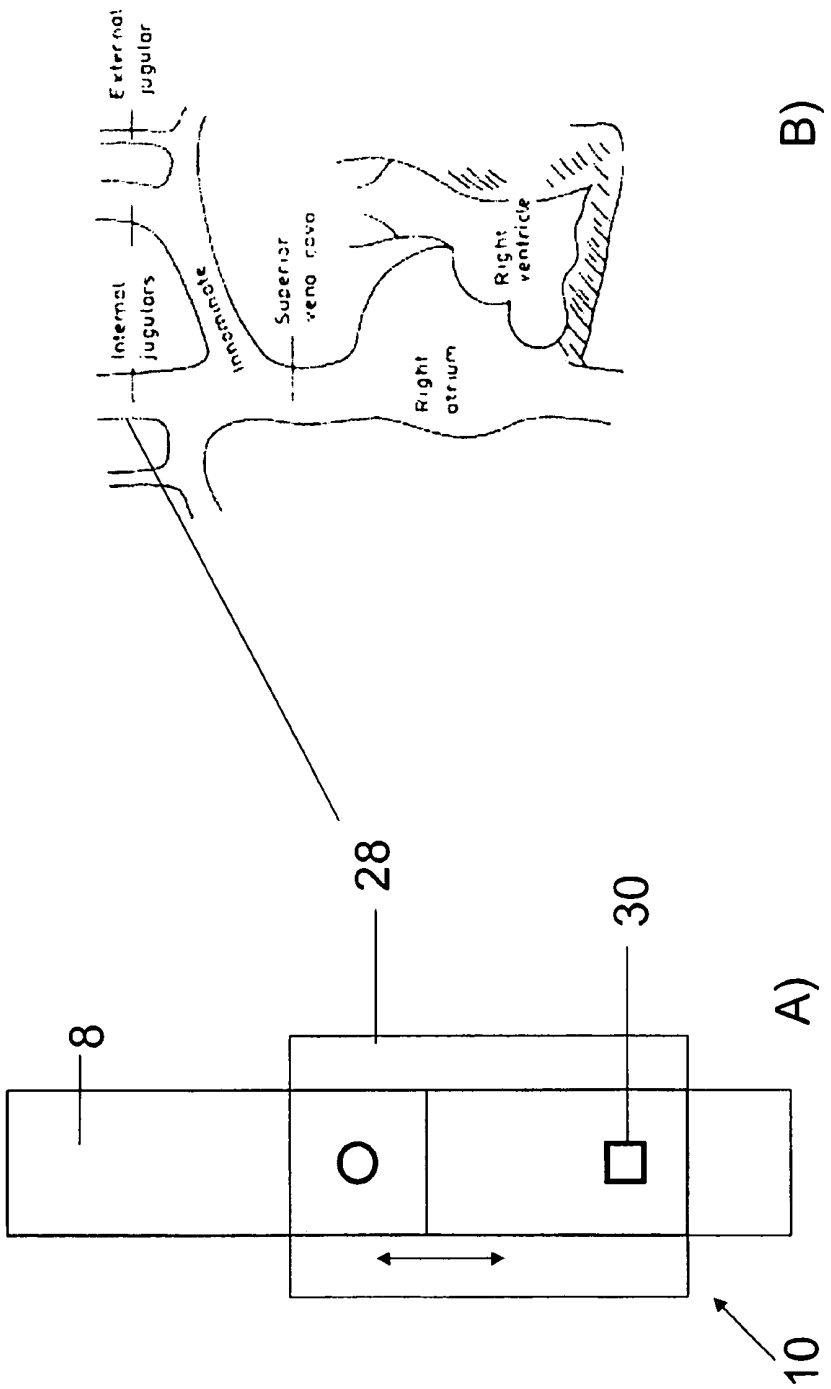

External jugular
Internal jugulars
Innominate
Superior vena cava
Right ventricle
Right atrium
B)
28
30
8
A)
10

Figure 1

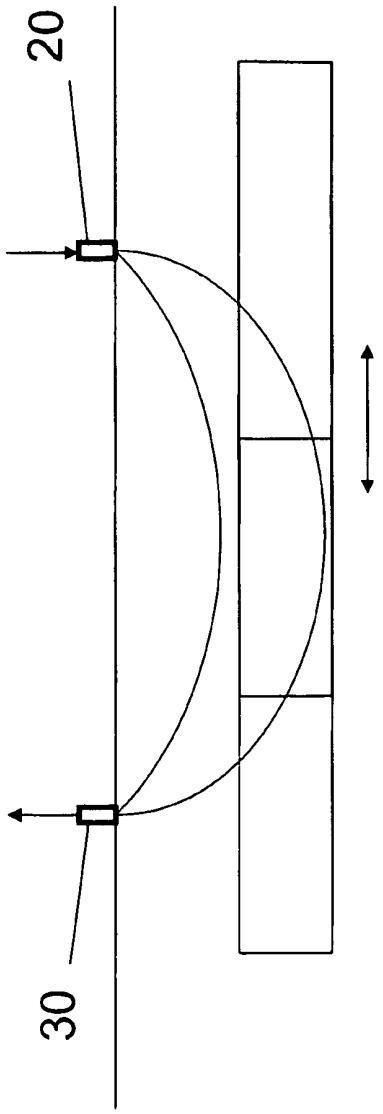


Figure 2

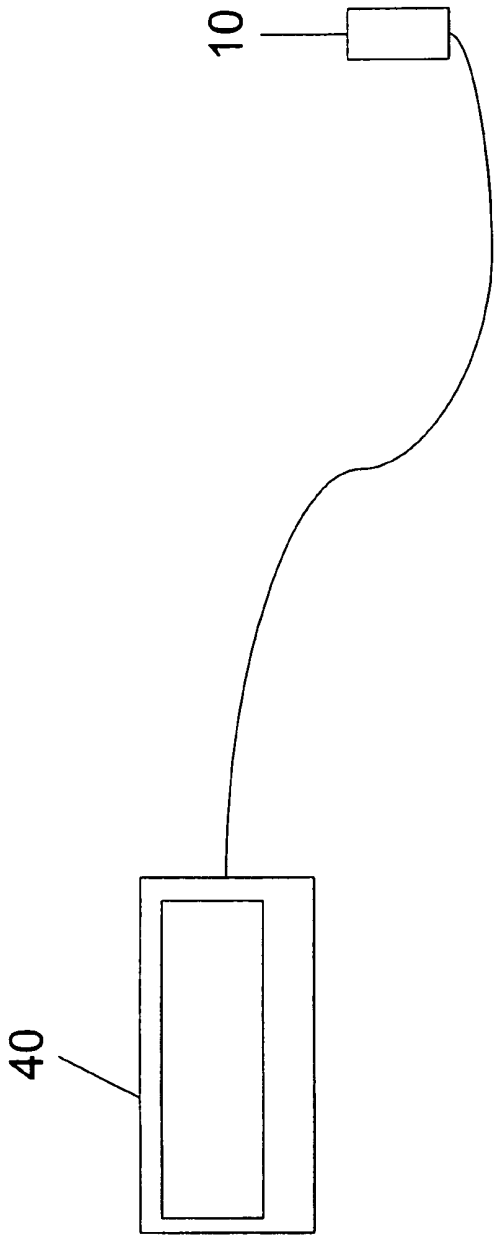


Figure 3

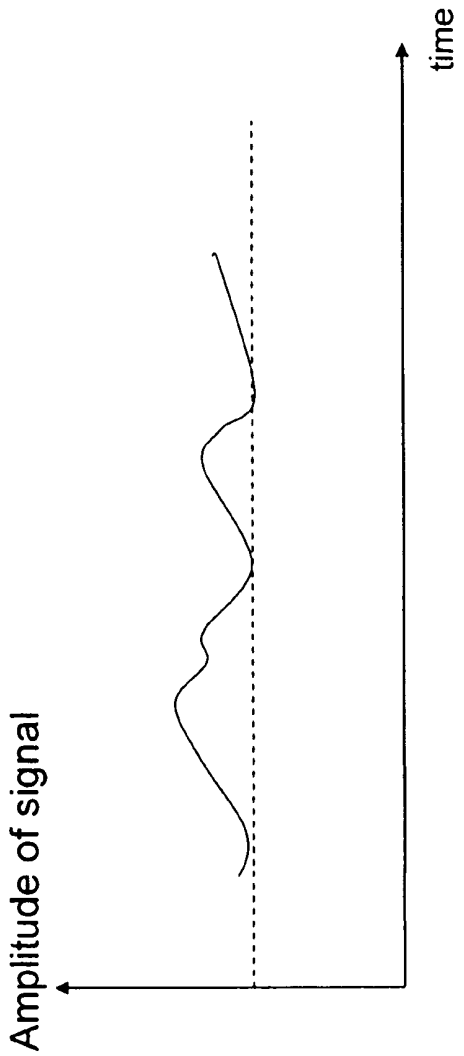


Figure 4

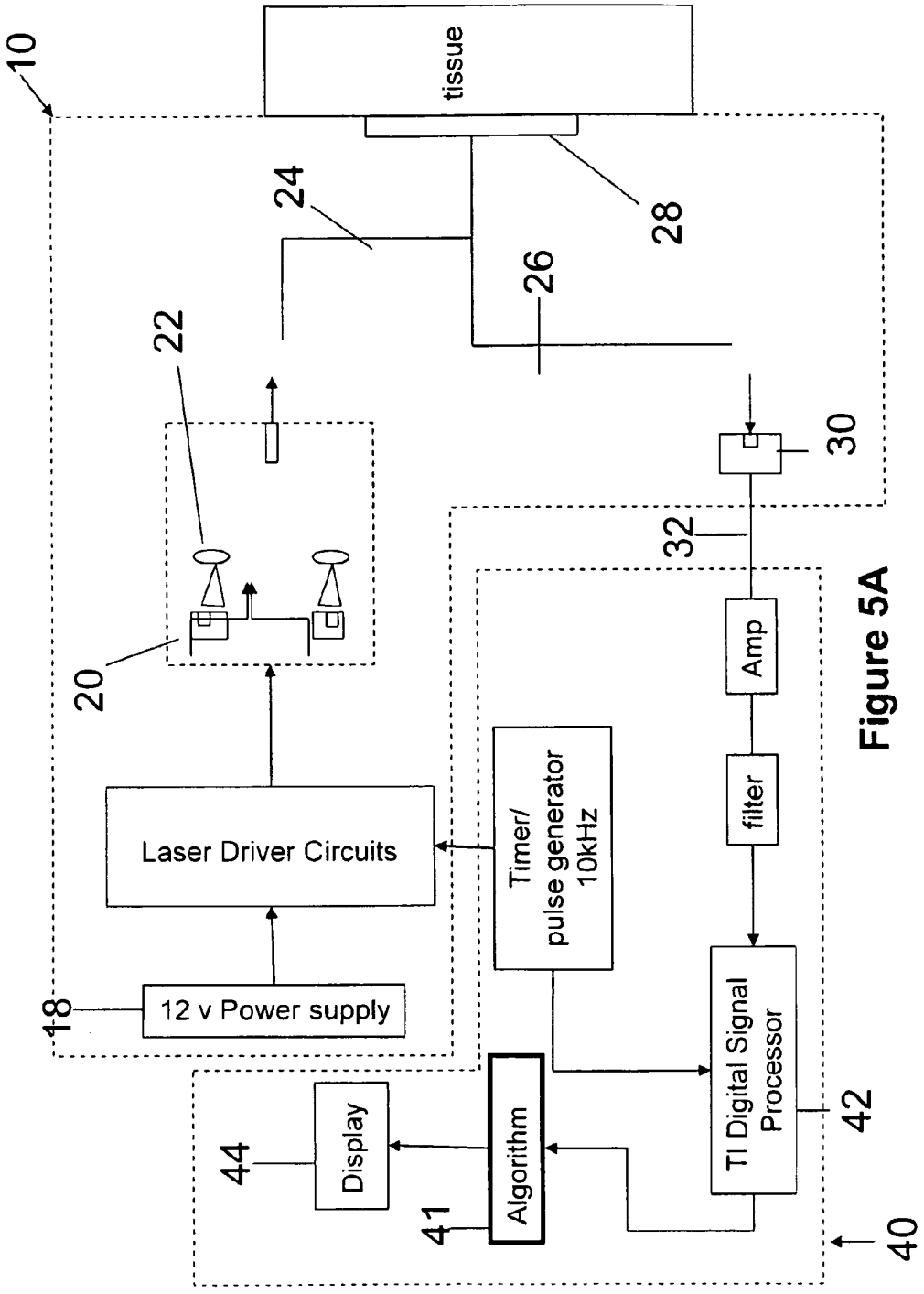

10
tissue
24
28
26
22
30
32
20
Amp
filter
Laser Driver Circuits
Timer/
pulse generator
10kHz
18
12 v Power supply
TI Digital Signal
Processor
42
Display
Algorithm
44
41
40

Figure 5A

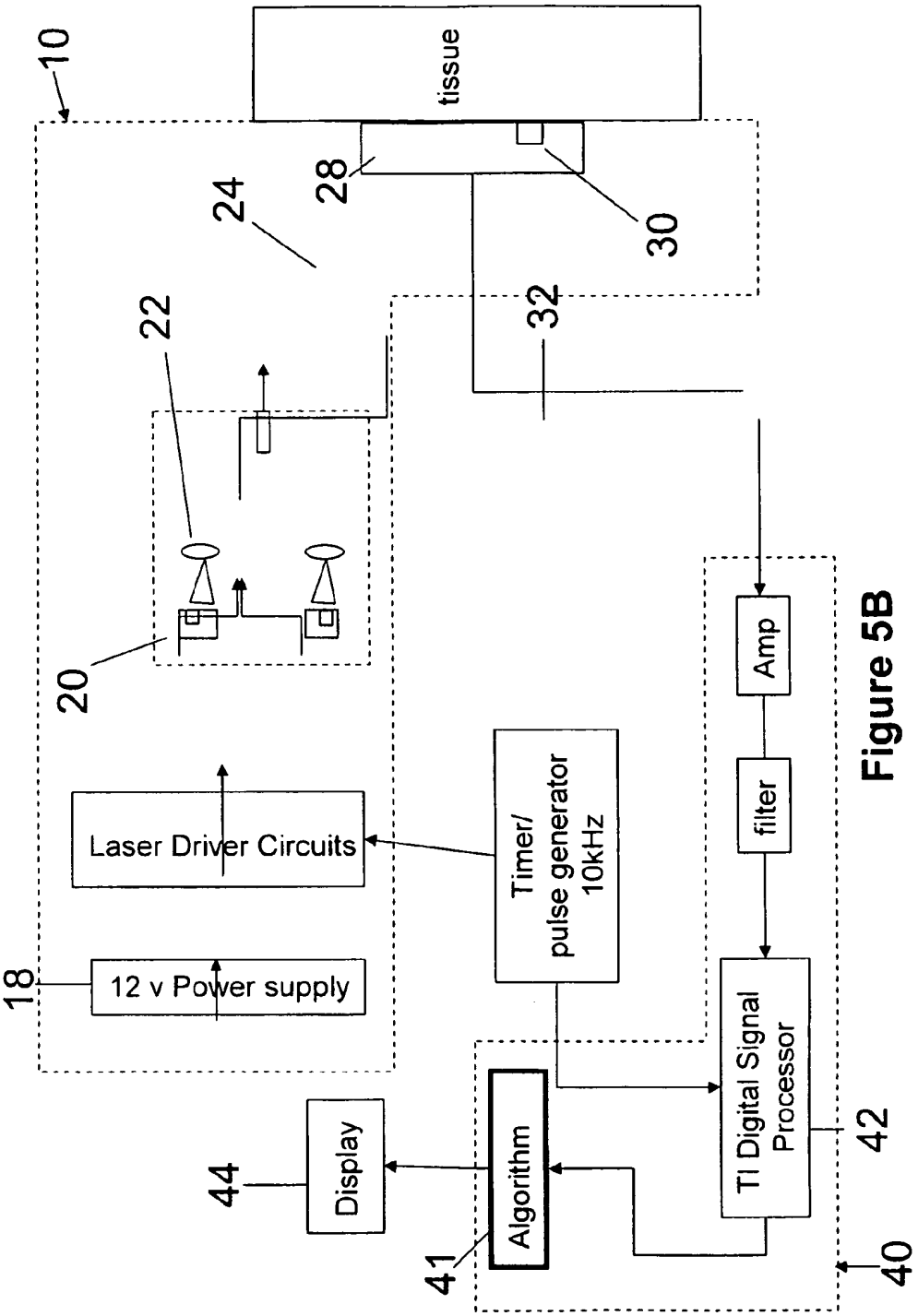

10
tissue
28
30
24
32
22
20
Amp
filter
Laser Driver Circuits
Timer/
pulse generator
10kHz
18
12 v Power supply
TI Digital Signal
Processor
42
Display
Algorithm
44
41
40

Figure 5B

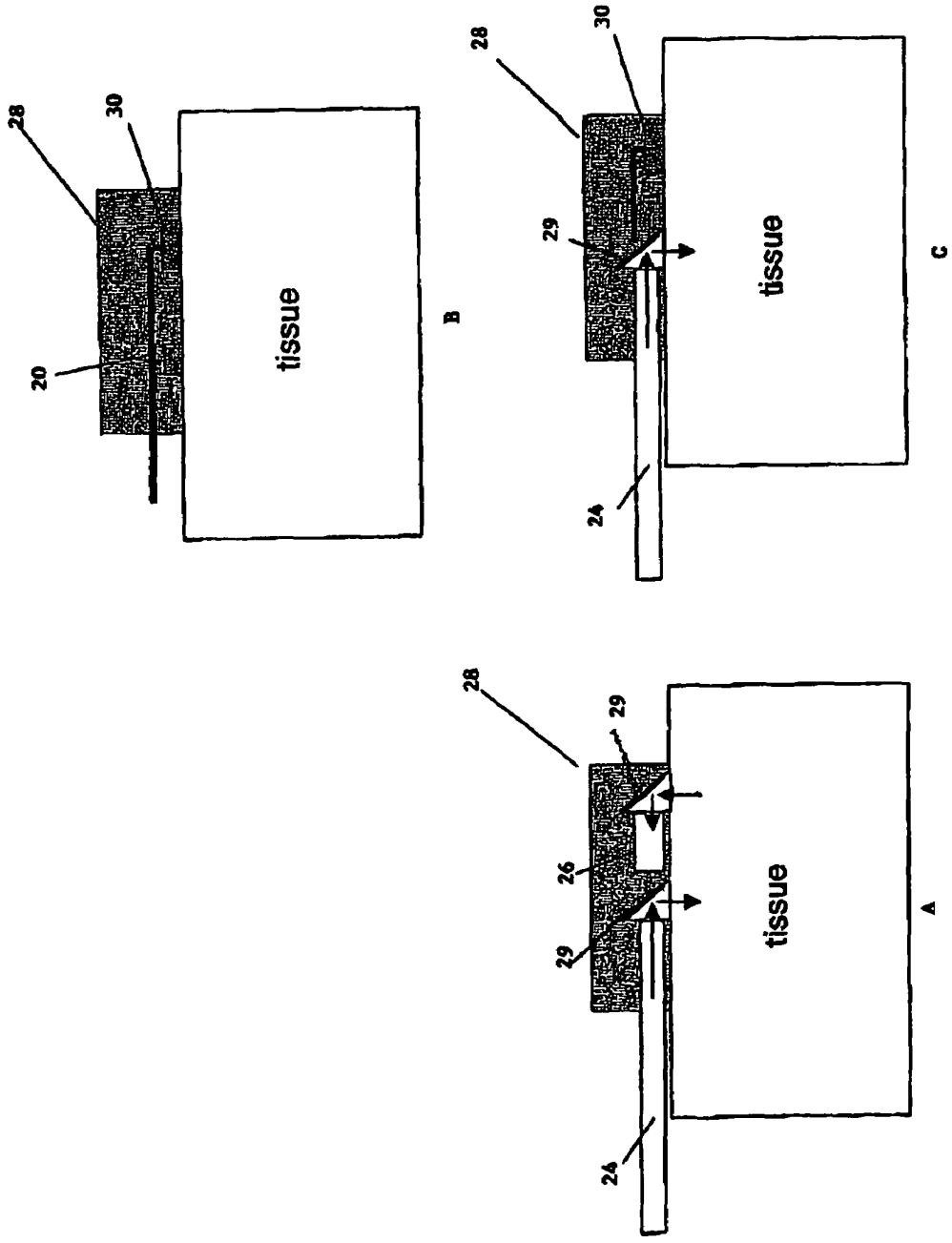


Figure 6

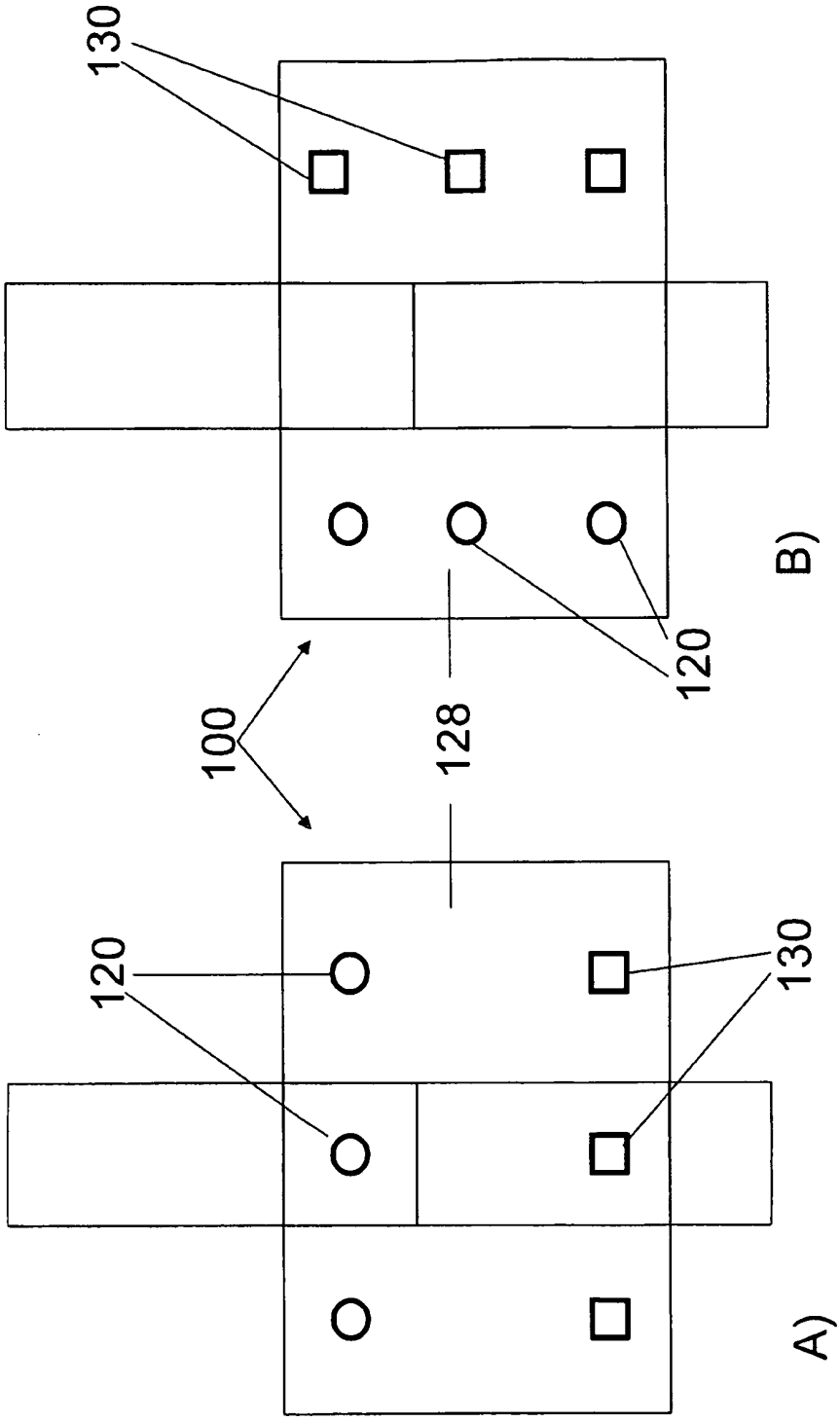


Figure 7

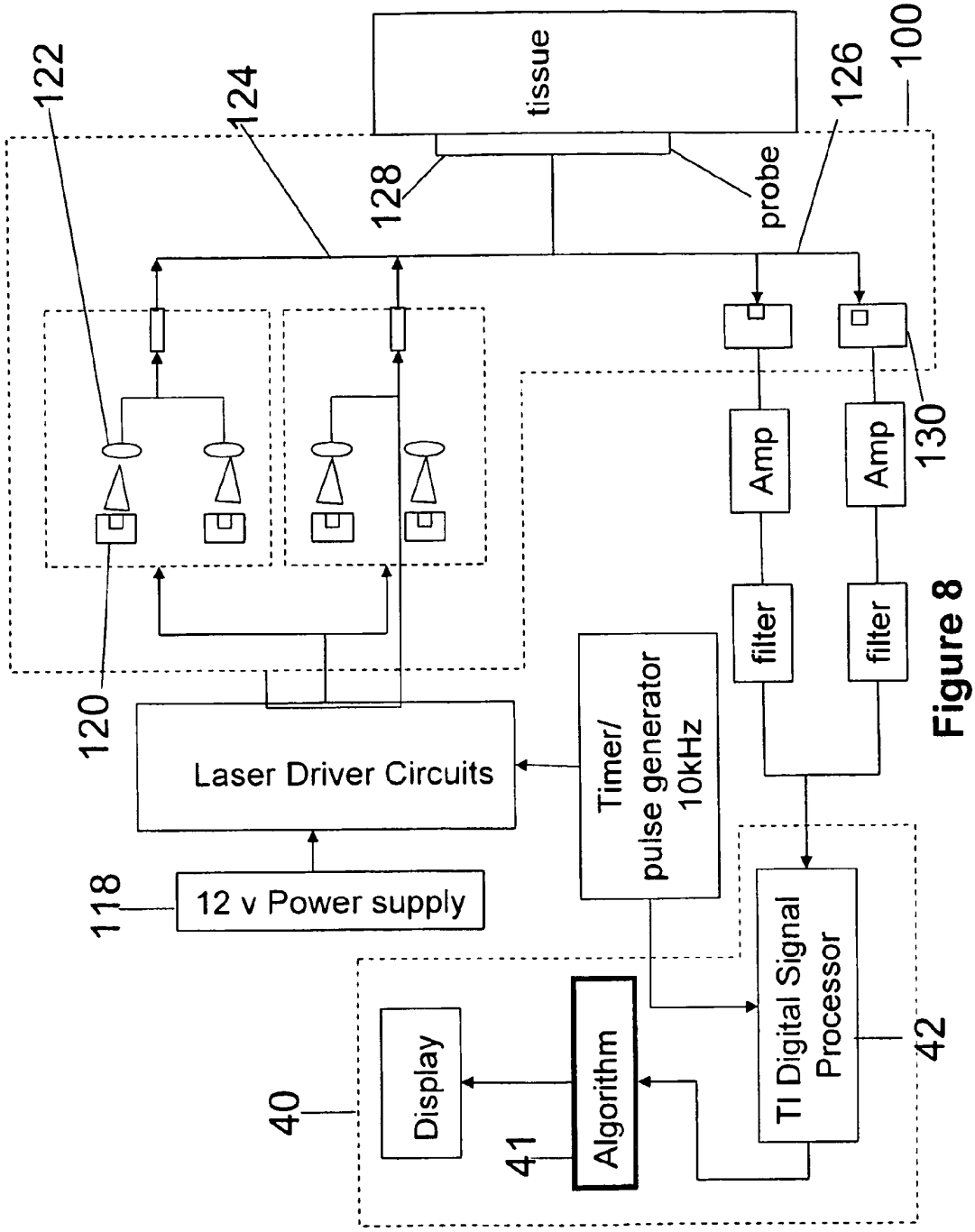
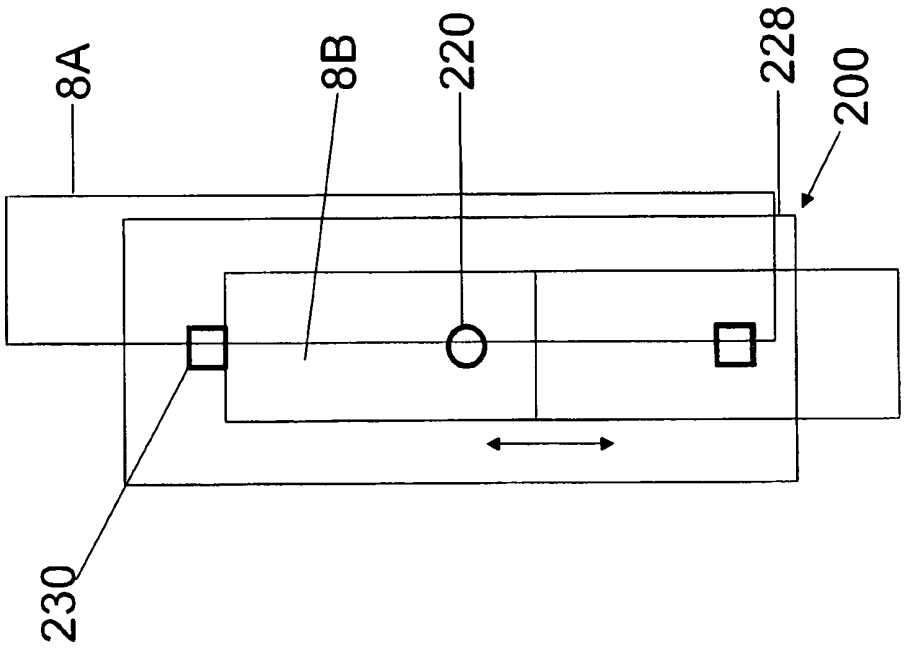

tissue
probe
122
124
126
100
128
130
Amp
Amp
filter
filter
120
Laser Driver Circuits
Timer/
pulse generator
10kHz
118
12 v Power supply
TI Digital Signal
Processor
42
40
Display
41
Algorithm

Figure 8



A)

Figure 9

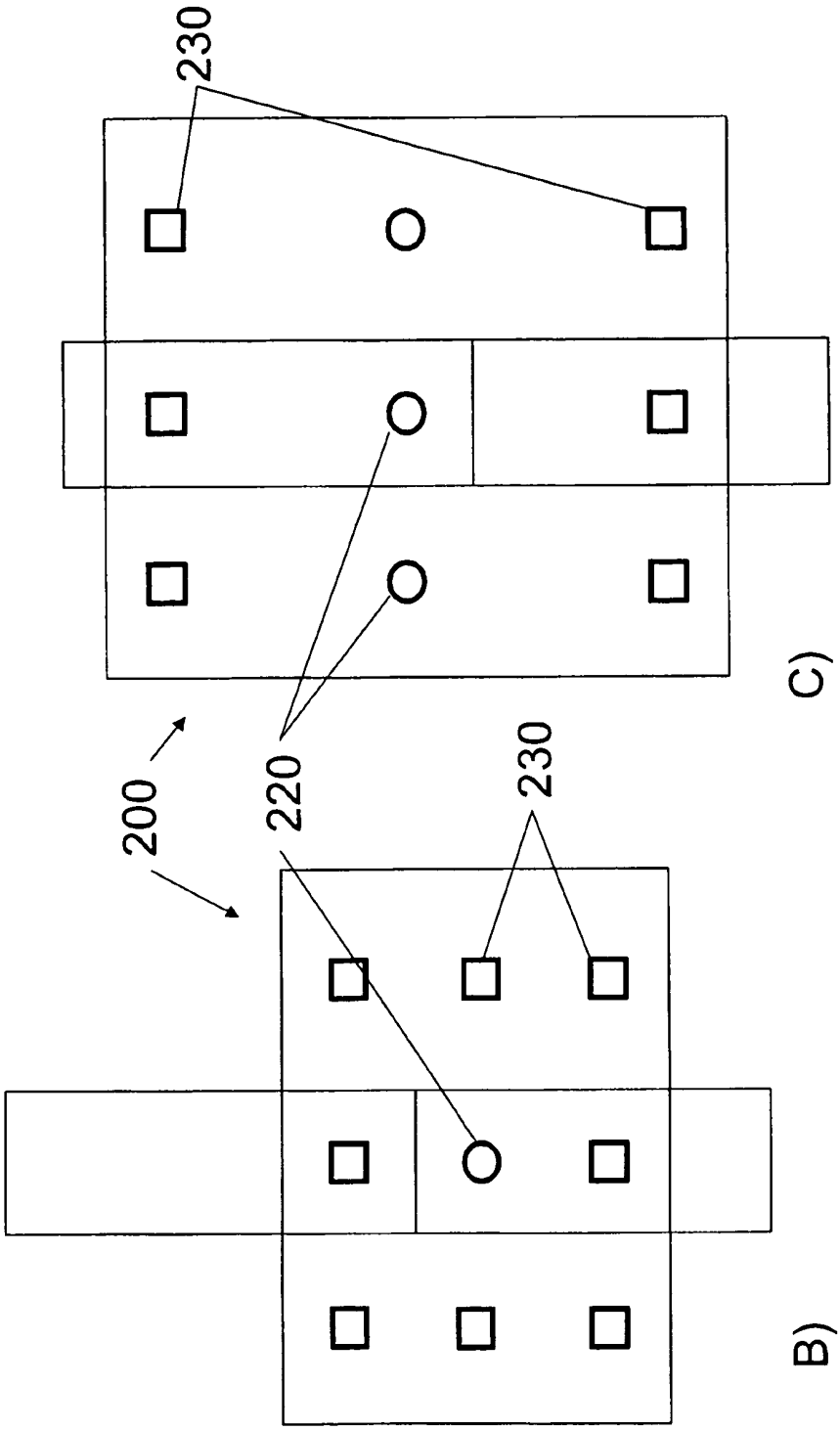


Figure 9

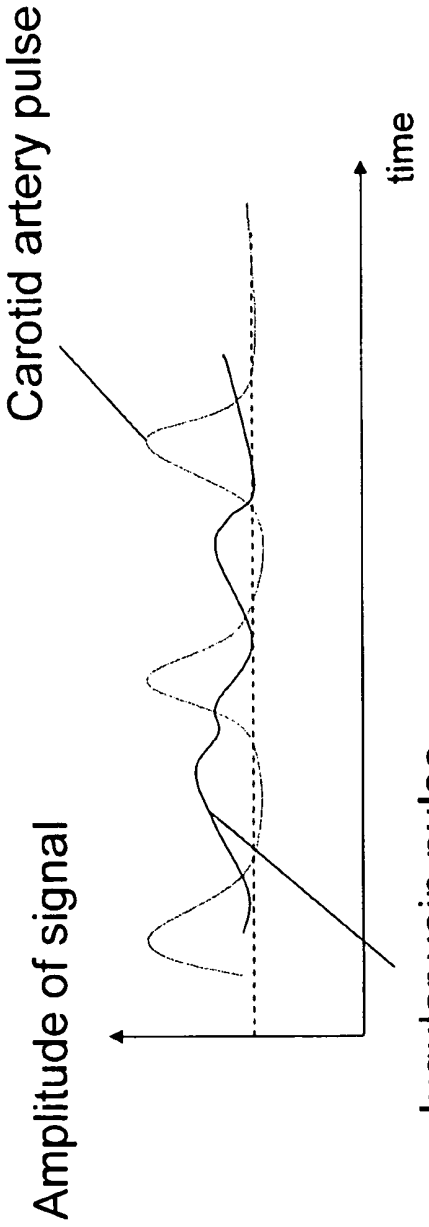

Carotid artery pulse
time
Amplitude of signal
Jugular vein pulse

Figure 10

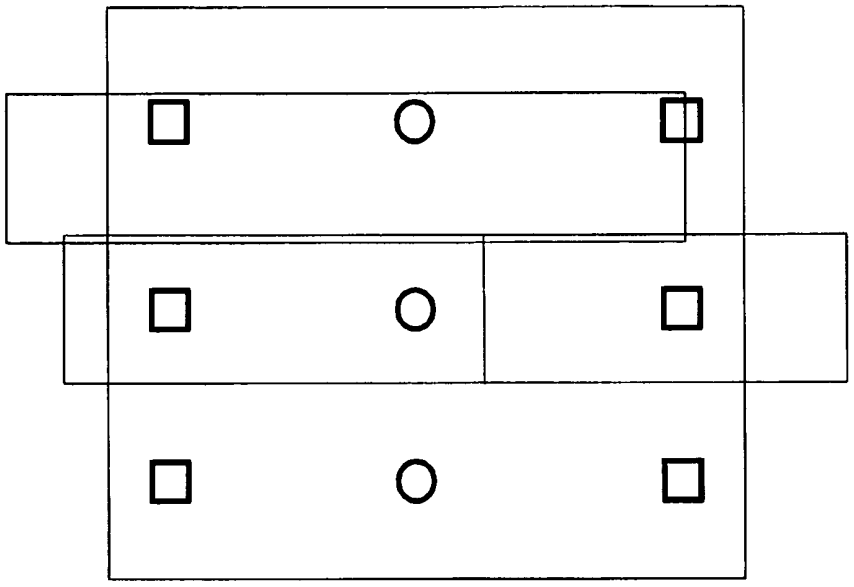


Figure 11

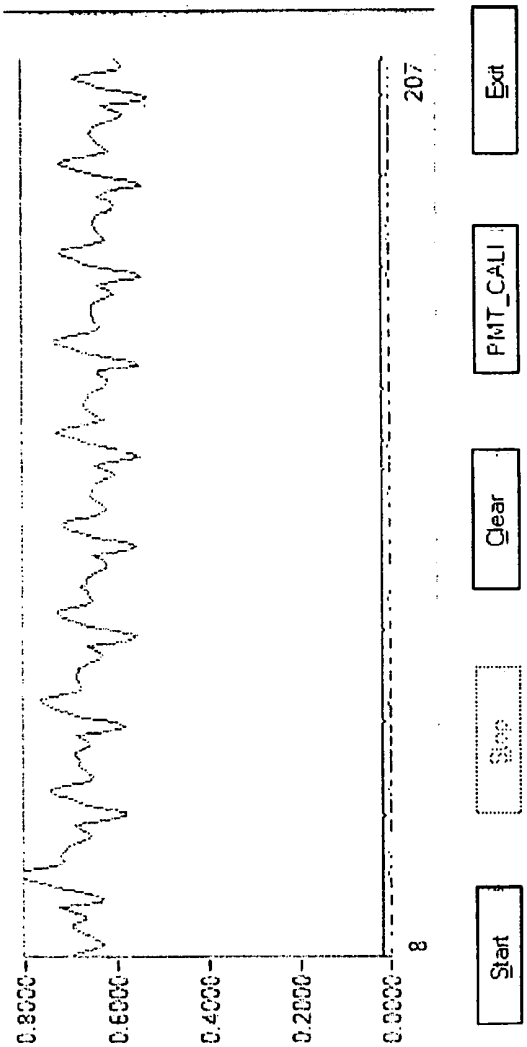

0.8000
0.6000
0.4000
0.2000
0.0000
8
207
Start
Stop
Clear
PMT_CALI
Exit

Figure 12

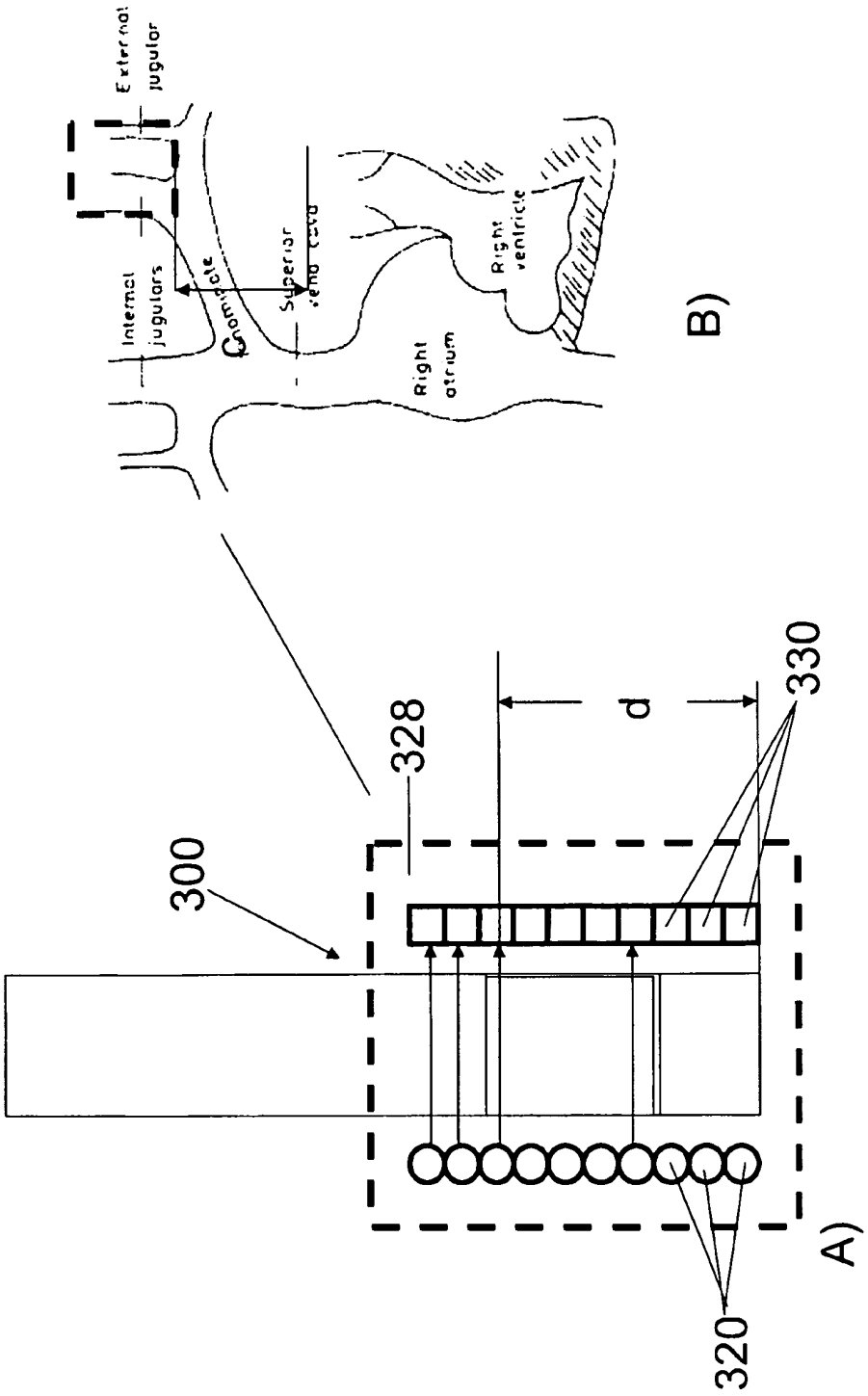

External jugular
Internal jugulars
Clavicle
Superior vena cava
Right atrium
Right ventricle
B)
300
328
d
330
320
A)

Figure 13

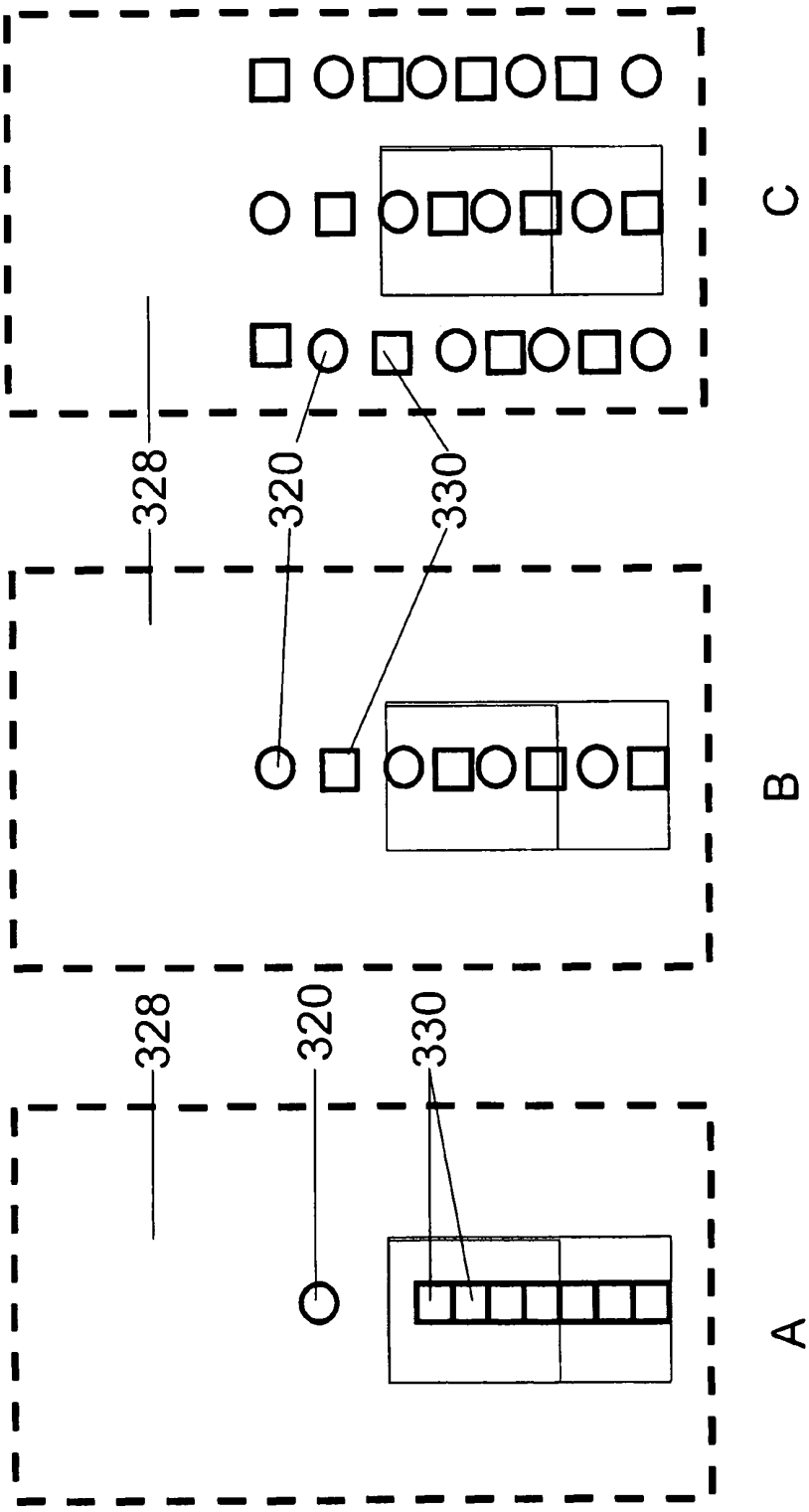


Figure 14

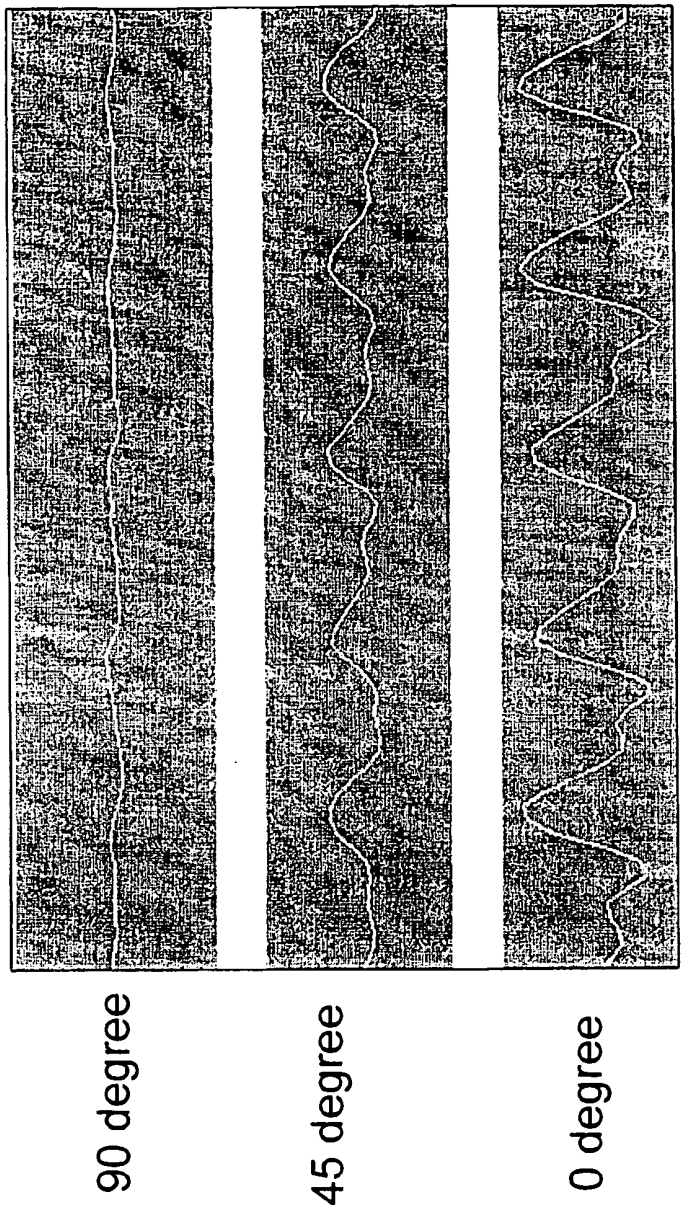


Figure 15

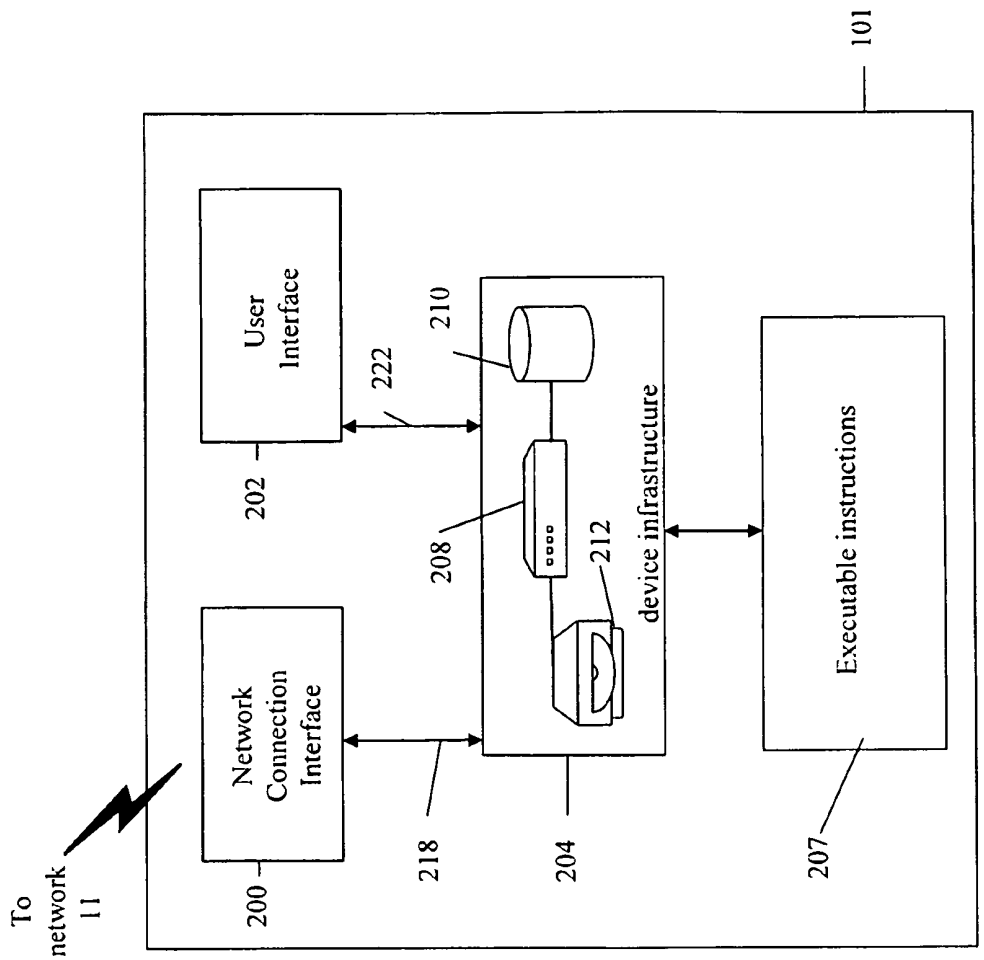

101
User Interface
202
222
210
208
212
device infrastructure
Executable instructions
207
Network Connection Interface
200
218
204
To network 11

Figure 16

METHOD AND DEVICE FOR MEASURING PARAMETERS OF CARDIAC FUNCTION

FIELD OF THE INVENTION

The present invention is related to techniques for monitoring vital functions of the human body, including cardiac functions such as cardiac output and central venous blood oxygenation. It relates, in particular, to an optical method and device for the non-invasive and continuous monitoring of cardiac parameters such as blood flow, blood volume and blood oxygen saturation.

BACKGROUND OF THE INVENTION

The evaluation of jugular venous pulse has been an integral part of cardiovascular examination and has important clinical diagnostic values [1-2]. Jugular venous pulse is produced by the changes in blood flow and pressure in central veins caused by right atrial and ventricular filling and contraction. The two main objectives of the bedside examination of jugular vein pulse include the estimation of central venous pressure and the inspection of the waveform. Because of its more direct route to the right atrium, the right internal jugular vein is superior for the purpose. Based upon these measurements, physicians can access hemodynamic events in the right atrium and thus diagnose heart diseases and abnormalities. For example, the most common cause of elevated jugular venous pressure is an increase in right ventricular pressure such as occurs in patients with pulmonary stenosis, pulmonary hypertension, or right ventricular failure secondary to right ventricular infarction. The venous pressure also is elevated when obstruction to right ventricular inflow occurs, such as with tricuspid stenosis or right atrial myxoma, or when constructive pericardial disease impedes right ventricular inflow. It may also result from vena caval obstruction and, at times, an increased blood volume. Patients with obstructive pulmonary disease may have an elevated venous pressure only during expiration.

The conventional technique for measuring venous pulse and waveform has been described in the literature [3]. The patient is examined at the optimum degree of trunk elevation for visualization of venous pulsations. The venous pressure is measured by a ruler as the vertical distance from the top of the oscillating venous column, to the level of the sternal angle plus vertical distance to the right atrium. Due to the fact that the venous pulse is in generally very small, and due to complications with patients, this method is challenging or physicians to use and provides approximate values only.

Cardiac output is defined as the volume of blood circulated per minute. It is equal to the heart rate multiplied by the stroke volume (the amount ejected by the heart with each contraction). Cardiac output is of central importance in the monitoring of cardiovascular health [4]. Accurate clinical assessment of circulatory status is particularly desirable in critically ill patients in the ICU and patients undergoing cardiac, thoracic, or vascular interventions, and has proven valuable in long term follow-up of outpatient therapies. As a patient's hemodynamic status may change rapidly, continuous monitoring of cardiac output will provide information that allows rapid adjustment of therapy. Measurements of cardiac output and blood pressure can also be used to calculate peripheral resistance.

Jansen (J. R. C. Jansen, "Novel methods of invasive/non-invasive cardiac output monitoring", Abstracts of the 7th annual meeting of the European Society for Intravenous Anesthesia, Lisbon 2004) describes eight desirable characteristics for cardiac output monitoring techniques; accuracy, reproducibility or precision, fast response time, operator independency, ease of use, continuous use, cost effectiveness, and no increased mortality and morbidity.

Pulmonary artery catheter (PAC) thermodilution method is generally accepted as the clinical standard for monitoring cardiac output, to which all other methods are compared as discussed by Conway and Lund-Johansen [6]. As this technology is highly invasive, complicated, and expensive, many new methods have been developed in an attempt to replace it, but none have so far gained acceptance. A recent review of the various techniques for measuring cardiac output is given in Linton and Gilon [5]. This article lists both non/minimally invasive and invasive methods and compares the advantages and disadvantages of each. A brief description of some of these techniques follows.

Indicator dilution techniques. There are several indicator dilution techniques including transpulmonary thermodilution (also known as PiCCO technology, Pulsion Medical Technologies of Munich, Germany), transpulmonary lithium dilution method (LiDCO Group plc or London, UK), PAC based thermo-dilution and other methods (Vigilance, Baxter; Opti-Q, Abbott; and TruCCOMS, AorTech). Application of such techniques assumes three major conditions, namely, complete mixing of blood and indicator, no loss of indicator between place of injection and place of detection, and constant blood flow. The errors associated with indicator dilution techniques are primarily related to the violation of these conditions, as discussed by Lund-Johansen [7-8].

Fick principle. The direct oxygen Fick approach is currently the standard reference technique for cardiac output measurement as discussed by Keinanen et al [9-10]. It is generally considered the most accurate method currently available. The NICO (Novametrix) system is a non-invasive device that applies Fick's principle and relies solely on airway gas measurement as described by Botero et al [11]. This method shows a lack of agreement between thermodilution and CO_2-rebreathing cardiac output as described in Nielsson et al [12], due to unknown ventilation/perfusion inequality in patients.

Bio-Impedance and conduction techniques. The bio-impedance method was developed as a simple, low-cost method that gives information about the cardiovascular system and/or (de)-hydration status of the body in a non-invasive way. Over the years, a diversity of thoracic impedance measurement systems have also been developed. These systems determine CO on a beat-to-beat time basis. Studies have been reported with mostly poor results, but in some exceptional cases, there was good correlation with a reference method. Many of these studies refer to the poor physical principles of the thoracic impedance method as described in Patterson "Fundamentals of impedance cardiography", IEEE Engineering in Medicine and Biology 1989; 35 to explain the discrepancies.

Echo-Doppler ultrasound. This technique uses ultrasound and the Doppler Effect to measure cardiac output. The blood velocity through the aorta causes a 'Doppler shift' in the frequency of the returning ultrasound waves. Echo-Doppler probes positioned inside the esophagus with their echo window on the thoracic aorta may be used for measuring aortic flow velocity, as discussed by Schmidlin et al [13]. Aortic cross sectional area is assumed in devices such as the CardioQ, made by Deltex Medical PLC, Chichester, UK, or measured simultaneously as, for example, in the HemoSonic device made by Arrow International. With these minimally invasive techniques what is measured is aortic blood flow, not cardiac output. A fixed relationship between aortic blood flow and cardiac output is assumed. Echo-Doppler ultrasound

requires an above average level of skill on the part of the operator of the ultrasound machine to get accurate reliable results.

Arterial pulse contour analysis. The estimation of cardiac output based on pulse contour analysis is an indirect method, since cardiac output is not measured directly but is computed from a pressure pulsation on the basis of a criterion or model [14-17]. Three pulse contour methods are currently available; PiCCO (Pulsion), PulseCO (LiDCO) and Modelflow (TNO/BMI). All three of these pulse contour methods use an invasively measured arterial blood pressure and they need to be calibrated. PiCCO is calibrated by transpulmonary thermodilution, LiDCO by transpulmonary lithium dilution and Modelflow by the mean of 3 or 4 conventional thermodilution measurements equally spread over the ventilatory cycle.

Near infrared spectroscopy has been used to non-invasively measure various physiological properties in animal and human subjects. The basic principle underlying near infrared spectroscopy is that a physiological medium such as tissues includes a variety of light-absorbing (chromophores) and light-scattering substances which can interact with transmitted low energy near infrared photons. For example, deoxygenated and oxygenated hemoglobins in human blood are the most dominant chromophores in the spectrum range of 400 nm to 1000 nm. Therefore, diffuse optical spectroscopy has been applied to non-invasively measure oxygen levels in the physiological medium in terms of tissue hemoglobin oxygen saturation. Technical background for diffuse optical spectroscopy has been discussed in, e.g., Neuman, M. R., Pulse Oximetry: Physical Principles, Technical Realization and Present Limitations.@ Adv. Exp. Med. Biol., vol. 220, p. 135-144, 1987 and Severinghaus, J. W., History and Recent Developments in Pulse Oximetry,@ Scan. J. Clin. and Lab. Investigations, vol. 53, p. 105-111, 1993.

Because of the highly scattering nature of tissue to the visible and near infrared light (400 nm-1000 nm), it is difficult to apply diffuse optical spectroscopy non-invasively to select blood vessels within a tissue to calculate blood oxygenation. Thus, diffuse optical spectroscopy has only been used to measure the combined or average oxygenation of blood from arteries, veins, and capillaries within a tissue medium. However, in many clinical applications, it is desirable to know the blood oxygenation of particular blood vessels. To do so, various invasive methods have been developed which involve the use of catheters that must be inserted into a targeted blood vessel to make the measurement.

None of the above-mentioned techniques of measuring cardiac output combines all of the eight "Jansen" criteria mentioned above and, thus, none can displace the conventional thermodilution technique as described by Jansen et al [18]. Although highly invasive, complicated and expensive, the conventional thermodilution method remains the method of choice for measuring cardiac output. Given the foregoing, it would be highly desirable to develop a non-invasive method for real-time monitoring of cardiac output in a clinical setting which is accurate, reliable, cost effective and easy to use.

SUMMARY OF THE INVENTION

The present invention provides a device, system and method by which cardiac parameters can be continuously monitored in a non-invasive manner by the optical measure of venous blood flow, venous blood pressure and blood content including oxygenation.

Thus, in one aspect of the invention, a device for non-invasively measuring at least one parameter of a cardiac blood vessel in a patient is provided comprising:

at least one light source that emits light in the 400 nm to 1000 nm wavelength range;

at least one photodetector adapted to receive light emitted by the light source and generate an output based on the received light, wherein said light is reflected from or transmitted through tissue of the patient, the output of said photodetector being correlated with a parameter of the blood vessel; and

at least one probe for facilitating delivery of light from the light source to an external tissue site on the patient in the proximity of the cardiac blood vessel and receipt of light by the photodetector.

In another aspect of the invention, a device useful to monitor a parameter of a cardiac blood vessel in a patient is provided comprising:

at least one light-emitting component adapted to emit light in the 400 nm to 1000 nm wavelength range;

at least one light-receiving component adapted to receive light emitted by the light-emitting component and translate said light into a recordable output, wherein said light is reflected from or transmitted through tissue of the patient; and

at least one probe which facilitates delivery of light from the light-emitting component to an external tissue site on the patient in the proximity of a cardiac blood vessel and receipt of light reflected from or transmitted through said patient site by the light-receiving component.

In another aspect of the invention, a system useful to monitor a parameter of a cardiac blood vessel in a patient is provided comprising:

at least one light-emitting component adapted to emit light in the 400 nm to 1000 nm wavelength range;

at least one light-receiving component adapted to receive light emitted by the light-emitting component and translate said light into a recordable output, wherein said light is reflected from or transmitted through tissue of the patient; and

at least one probe which facilitates delivery of light from the light-emitting component to an external tissue site on the patient in the proximity of a cardiac blood vessel and receipt of light reflected from or transmitted through said patient site by the light-receiving component; and

a signal-processing device adapted to translate the output from said light-receiving component to a visual form.

In another aspect of the invention, a method for determining a parameter of a cardiac blood vessel in a patient is provided comprising the steps of:

directing a beam of light having a wavelength in the range of 400 nm to 1000 nm to an external tissue site on the patient that is in the proximity of the blood vessel;

detecting light reflected from the tissue site or transmitted through the tissue site;

translating the detected light into an output signal against time; and

calculating the parameter of the blood vessel using the output signal.

In another aspect of the invention, a method for measuring the blood content of a chromophore in a patient is provided comprising:

directing a light beam having at least first and second selected wavelengths at an external tissue site on the patient that is in the proximity of a cardiac blood vessel, wherein said selected wavelengths are based on the absorption characteristics of the chromophore;

detecting light reflected from the tissue or transmitted through the tissue at the selected wavelengths; and

translating the detected light into an output current in order to determine the blood content of said chromophore according to modified Beer Lambert's law.

In a further aspect, a method of determining blood oxygenation of a cardiac vessel in a patient is provided comprising:

directing a first light beam having a first wavelength of 780 nm and a second light beam having a second wavelength of 850 nm at an external tissue site on the patient that is in the proximity of a cardiac blood vessel;

detecting light reflected from the tissue or transmitted through the tissue at the first and second wavelengths; and

translating the detected light into an output current for the first and second wavelengths in order to calculate the blood oxygenation of the cardiac vessel according to modified Beer Lambert's law.

In another aspect of the invention, s method of determining central venous pressure in a patient is provided comprising:

directing a beam of light having a wavelength in the range of 400 nm to 1000 nm at a series of external tissue sites on the patient along the jugular vein starting from the sternal angle;

detecting light reflected from the tissue site or transmitted through each tissue site;

translating the detected light into an output signal against time to determine the highest position along the vein to yield a signal (d); and

calculating the central venous pressure (P) according to the equation P=(d+5)sin 9, wherein 9 is the inclined body angle from horizontal of the patient.

These and other aspects of the present invention will become apparent by reference to the detailed description that follows, and the drawings in which:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates a top view of a device (A) for monitoring cardiac output in accordance with an aspect of the invention and placement of the device relative to cardiac vessels (B);

FIG. **2** illustrates a side view of a device as in FIG. **1**;

FIG. **3** illustrates a system incorporating the device of FIG. **1**;

FIG. **4** illustrates a signal or waveform produced using a device as in FIG. **1**;

FIGS. **5** (A and B) is a block diagram of a system incorporating a device as in FIG. **1**;

FIG. **6** (A-C) illustrates probes for use in the device;

FIG. **7** illustrates a top view of embodiments of the invention (A, B) comprising multiple light sources and photodetectors;

FIG. **8** is a block diagram of a system incorporating a device as in FIG. **7**;

FIG. **9** (A-C) illustrates a top view of embodiments of the invention comprising multiple photodetectors per light source;

FIG. **10** illustrates a dual signal (waveform) generated by an embodiment of FIG. **9**;

FIG. **11** illustrates a top view of a cardiac monitoring device according to an embodiment of the invention comprising multiple sensor patches;

FIG. **12** illustrates a waveform obtained using a device in accordance with the invention;

FIG. **13** illustrates a top view of a device in accordance with a further aspect of the invention;

FIG. **14** illustrates different source-detector configurations (A, B and C) of a device useful to measure blood pressure;

FIG. **15** illustrates a waveform obtained using a device according to FIG. **13** (B) in three different positions (A); and

FIG. **16** is a block diagram illustrating a system according to an aspect of the invention.

DETAILED DESCRIPTION OF THE INVENTION

A device **10** for measuring a parameter of cardiac function in a patient is provided as shown in FIG. **1**A, comprising a light source **20** that emits light in the 400 nm to 1000 nm wavelength range, e.g. visible and infra-red light, a photodetector **30** adapted to receive light from the light source **20** (as shown in FIG. **2**) and translate the received light into an output signal and a patch probe **28** for placement on a patient at an external site in the vicinity of a cardiac blood vessel (as shown in FIG. **1**B) which functions as the interface of the device between light source **20**/photodetector **30** and a selected external patient site. Thus, the probe **28** permits/facilitates delivery of light emitted by the light source **20** to the selected patient site and transfer of light reflected from or transmitted through the patient site to the photodetector **30**. To generate a visual signal, the device **10** may additionally comprise a signal-processing component **40** (FIG. **3**) which communicates with the photodetector **30** to translate light received by the photodetector **30** into a recordable visual signal or waveform of the cardiac vessel (e.g. representative of a time course plot of a measurable characteristic or parameter of the blood vessel such as a pressure waveform or central venous pulse).

The light source **20** may be any suitable light source such as a laser diode (e.g. RLT7605G, 760 nm, 5 mW, sm, 9.0 mmh, or RLT8510MG, 850 nm, 10 mW, sm, 5.6 mm), a light emitting diode (LED) or a broadband light source emitting a selected wavelength in the range of 400 nm to 1000 nm, for example, a wavelength in the range of 780 nm and 850 nm. In an embodiment, the light source is adapted to emit light in two or more wavelengths, e.g. by association with a frequency oscillator. The light source **20** is powered by an appropriate power supply **18** such as a 12V DC power supply. Light from the light source **20** is directed to at least one external tissue site on the patient that is within close proximity to a cardiac blood vessel, such as the internal jugular vein, the external jugular vein and the carotid artery, while the internal jugular vein is preferred. The neck, for example, represents a suitable site for monitoring a cardiac parameter.

As shown in FIG. **5**A/**5**B, in one embodiment, light from the light source **20** may be directed or focused by an optical lens **22** into a transmitting means **24**, such as transmitting optical fibre bundles, for transmission to the selected patient site. Receiving means **26**, such as optical fibre bundles, may also be used to receive light that is reflected/transmitted from the patient site and convey this light to photodetector **30** (FIG. **5**A). As one of skill in the art will appreciate, each fibre optic bundle will incorporate fibres manufactured of material appropriate for the transmission of the wavelength of the light emitted from the light source **20**. For example, if the light source **20** emits in the visible wavelength range, both multiple mode plastic and glass optical fibres may be used. The number and diameter of the fibres in the fibre optic bundle is optimized empirically to provide the highest signal to noise ratio in a given application. In the embodiments shown in FIG. **5**A/**5**B, the transmitting and receiving optical fibre bundles **24**, **26** are set in the patch probe **28**, either at distinct spaced sites or they may be combined together at a single site.

As shown in FIG. **6**A/**6**C, optical mirrors **29** may be utilized to direct or reflect light from the transmitting fibre bundle **24** into the tissue at the selected patient site, and to direct reflected or transmitted light from the patient site into the receiving fibre bundle **26** (FIG. **6**A). Alternatively, the light source **20** and photodetector **30** may be set directly in the patch probe **28** obviating the need for optical fibres as shown in FIG. **6**B. In yet another embodiment, a combination of the foregoing embodiments may be utilized in which the light source **20** is set directly in the probe **28** to deliver light to the patient site, while the reflected/transmitted light is received by optical fibres **26** for delivery to the photodetector **30**. A converse embodiment may also be used in which the probe **28**

comprises transmitting optical fibres **24** to deliver light from the light source to the patient site, and a photodetector **30** set directly in the probe **28** to receive the reflected/transmitted light (FIG. **6**C). Accordingly, the light source **20** and photodetector **30** are each coupled to the probe **28** (e.g. attached to, integrally formed with or set directly in the probe **28**).

The light source **20** or transmitting optical fibres **24** may be set in the same patch probe **28** as the photodetector **30** or receiving optical fibres **26**, or in a separate patch probe **28** for placement at a distinct site on the patient that is within a suitable distance from the photodetector **30** or receiving optical fibres **26** to permit detection of reflected/transmitted light. The distance between the component delivering light to the patient site (light source or transmitting optical fibres) and the component receiving light from the patient site (photodetector or receiving optical fibres) may vary depending on the nature of each of the components, while a typical distance is generally between 2 and 4 cm, for example, 3 cm.

The patch probe **28** may be made out of any material suitable to support the electronic/optical components it houses, e.g. light source, photodetector, optical fibres or mirrors, and which is compatible for placement on the skin. An example of one such suitable material is medical rubber. The patch **28** may be held in position manually, may be held in position by adhesives (one side of the patch may be coated with a material that is adhesive to skin such as a hydro gel adhesive) or may be adapted to be held in place with straps that can be tied or otherwise secured. Opposing ends of the band may also include an adhesive material such as Velcro to facilitate their attachment and to hold the device in place.

The photodetector **30** translates received reflected/transmitted light into a recordable output such as current or voltage. An example of a suitable photodetector **30** for use in the present device is a silicon photo diode (e.g. Hamamatsu S8553). Condensor lenses may be incorporated, if required, to refocus the reflected or transmitted beam of light to be received by the photodetector **30**. As will be understood by a person skilled in the art, silicon photodiodes are semiconductor light sensors that generate a current or voltage when the P-N junction in the semiconductor is illuminated by light. Accordingly, the photodetector **30** provides a current/voltage signal in response to the received light signal. Thus, the current/voltage signal output generated by the photodetector **30** is proportional to the instantaneous light intensity of the light signal received at the photodetector **30**. Accordingly, the photodetector **30** provides a time-varying output (e.g. current/voltage as a function of time) which is dependent upon the received light and its characteristics.

In an aspect of the invention, a system is provided, for example as shown in FIGS. **5**. **8** or **16**, in which the photodetector **30** of device **10** is connected to a signal processing device **40**. The signal processing device **40** is operable to receive the signal provided by the photodetector **30** (e.g. the time varying current/voltage signal) and translate the signal into a visual output such as a waveform. Thus, the signal processing device **40** is operable to digitize the output provided by the photodetector **30** into a recordable output for presenting on a display (e.g. **44**).

Referring to FIG. **5** or **8**, a system is provided comprising at least one light source **20** for emitting light, a probe **28** for facilitating the delivery of light to an external tissue site on the patient, at least one photodetector **30** configured for receiving light emitted by the light source **20** (which is either reflected from or transmitted through the tissue site) and translating the light to a current/voltage signal in response thereto, a signal processing device **40** for translating the signal from the photodetector **30** into a visual output such as a time-varying waveform. As will be described below, the signal processing device **40** may include a microprocessor (e.g. digital signal processor, Texas Instruments) or digital acquisition board **42** to digitize the signal (e.g. current/voltage) from the photodetector **30**, and a display unit **44**, such as a monitor, which is in communication with or connected to the microprocessor **42** (FIG. **5**), and functions to display the signal as a waveform.

Alternatively, as will be understood by a person of skill in the art and as shown in FIG. **5**B, the signal processing device **40** may be separate from the display unit **44**, and in communication with an external display unit **44** for presenting the output of the signal processing device **40** thereon. For convenience, the monitor may be portable, and battery operated. According to another embodiment, the signal processing device **40** may further comprise an algorithm processing module **41** (e.g. illustrated in FIG. **8**) for receiving an indication of the desired cardiac parameter output (e.g. via a user interface or predefined selection of the desired cardiac parameter). The algorithm processing module **41** is operable to translate the signal received from the photodetector **30** into the desired cardiac parameter output (e.g. blood pressure waveform).

Referring to FIG. **16**, the signal processing device **40** can be implemented on one or more respective computing device(s) **101**. The devices **101** in general can include a network connection interface **200**, such as a network interlace card or a modem, coupled via connection **218** to a device infrastructure **204**. The connection interface **200** is connectable during operation of the device(s) **101** to a network **11** (e.g. an intranet and/or an extranet such as the Internet) which enables the device(s) **101** to communicate with each other as appropriate. The network **11** can, for example, support the communication of the output signal (e.g. current/voltage signal) provided by the photodetector **30** to the signal processing device **40**.

The device(s) **101** may also have a user interface **202**, as also shown in FIG. **16**, coupled to the device infrastructure **204** by connection **222** to interact with a user. The user interface **202** can include one or more user input devices such as, but not limited to, a QWERTY keyboard, a keypad, a trackwheel, a stylus, a mouse, a microphone and a user output device such as an LCD screen display and/or a speaker. If the screen is touch sensitive, then the display can also be used as the user input device as controlled by the device infrastructure **204**.

Operation of the device(s) **101** is facilitated by the device infrastructure **204**. The device infrastructure **204** includes one or more computer processors **208** (e.g. a Digital Signal Processor) and can include an associated memory **210** (e.g. a random access memory). The computer processor **208** facilitates performance of the computing device **101** configured for the intended task through operation of the network interface **200**, the user interface **202** and other application programs/hardware **207** of the computing device **101** by executing task-related instructions. These task-related instructions may be provided by an operating system and/or software applications **207** located in the memory **210**, and/or by operability that is configured into the electronic/digital circuitry of the processor(s) **208** designed to perform the specific task(s). Further, it is recognized that the device infrastructure **204** may include a computer readable storage medium **212** coupled to the processor **208** for providing instructions to the processor **208**. The computer readable medium **212** can include hardware and/or software such as, by way of example only, magnetic disks, magnetic tape, optically readable medium such as CD/DVD ROMS, and memory cards. In each case, the computer readable medium **212** may take the form of a small disk, floppy diskette, cassette, hard disk drive,

solid-state memory card or RAM provided in the memory module **210**. It should be noted that the above listed examples of computer readable media **212** may be used either alone or in combination. The device memory **210** and/or computer readable medium **212** may be used to store, for example, the desired output (e.g. pressure waveform) for use in processing of the signal received from the photodetector **30**.

Further, it is recognized that the computing device(s) **101** may include executable applications **207** comprising code or machine readable instructions for implementing predetermined functions/operations including those of an operating system. The processor **208** as used herein is a configured device and/or set of machine-readable instructions for performing operations as described by example above. As used herein, the processor **208** may comprise any one or combination of, hardware, firmware, and/or software. The processor **208** acts upon information by manipulating, analyzing, modifying, converting or transmitting information for use by an executable procedure or an information device, and/or by routing the information with respect to an output device. The processor **208** may use or comprise the capabilities of a controller or microprocessor, for example. Accordingly, the functionality of the signal processing device **40** and/or the photodetector **30** may be implemented in hardware, software or a combination of both. Accordingly, the use of a processor **208** as a device and/or as a set of machine-readable instructions is hereafter referred to generically as a processor/module for the sake of simplicity.

It will be understood that the computing device(s) **101** may be, for example, personal computers, personal digital assistants, mobile phones, and content players. Further, it is recognised that each server computing device **101**, although depicted as a single computer system, may be implemented as a network of computer processors, as desired.

Referring to FIG. **8**, the signal processing device **40** may execute an algorithm (e.g. via the algorithm processing module **41**) to translate the signal received by the photodetector **30** to a waveform. The waveform is the time varying component of the optical signal associated with cardiac activities, which can be translated into dynamic information such as blood flow, flow velocity, blood volume, blood pressure and blood content such as oxygenation or physical displacement of blood within the vessel.

In one embodiment, for example, the signal is translated into a pressure waveform. Since the central venous pressure waveform is proportional to the blood volume inside the jugular vein, and the amplitude of the received signal from the photodetector (e.g. the current/voltage signal) is inversely proportional to the blood volume, the central venous pressure waveform is constructed by an algorithm that inverts the signal received by the photodetector as follows:

$$P(t) \sim 1/S(t)$$

where P is the pressure waveform and S is the signal from photodetector (e.g. the current/voltage signal).

The absorbance values collected at regular user-determined intervals, for example, 10 data points/mm, are stored as a spreadsheet associated with a cardiac parameter or cardiac output. The display unit **44** functions in real-time to display the selected blood vessel waveform according to an executed algorithm (via the algorithm processing module **41**) against time which can be used as described below to calculate, for example, a cardiac parameter or cardiac output.

A sample display of a waveform (e.g. generated based on a signal obtained by the photodetector and processed by a signal processing device **40**) obtained using the present device is shown in FIG. **4**. As can be seen, there is a time course variation in the signal detected by the photodetector **30** that results from a selected blood vessel pulse, changes in the blood volume and content (such as oxygen saturation) inside the blood vessel. The blood volume and content in the selected blood vessel affects the absorption of light, thereby resulting in a signal with varying amplitude. For example, as the jugular vein pulse increases and decreases the blood volume in the jugular vein, the amplitude of the detected optical signal (e.g. as received by photodetector **30**) will decrease and increase, respectively. The time course plot of the amplitude of the recorded signal reflects the waveform of the jugular vein pulse.

In another embodiment of the present invention, a device **100**, operable to measure blood content, such as the blood oxygen saturation of central venous blood, is provided. As the jugular vein, especially the right internal jugular vein, is directly connected to the superior vena cava as shown in FIG. **1**, the jugular vein waveform is representative of the parameters of central venous blood.

For this utility, the device **100**, as shown in FIGS. **7** and **8**, comprises at least two light sources **120**, each emitting light of a different wavelength within the range of 400 nm to 1000 nm. The device also comprises a photodetector **130** for each light source **120** adapted to receive the transmitted or reflected light at a given wavelength. As set out above, each light transmitting component (e.g. light source **120** or transmitting optical fibres **124**) and light receiving component (e.g. photodetector **130** or receiving optical fibres **126**) is set in a patch probe **128**, and may be arranged as shown in FIG. **7**A or **7**B; however, as one of skill in the art will appreciate, alternative arrangements of the light-transmitting components and light-receiving components exist which will not affect the function of the device **100**. For example, the device **100** may comprise multiple patches probes **128**, each of which includes a light-transmitting component and a light-receiving component. Alternatively, the device **100** may comprise a single patch **128** including multiple light-transmitting components and light-receiving components. In another alternative, the device **100** may comprise a first patch **128** with one or more light-transmitting components and light-receiving components, and a second patch with one or more light-transmitting components and corresponding light-receiving components. As set out above, regardless of the number of patches and arrangements thereof, the device may be incorporated within a system as described above comprising a signal receiving device **140** and to translate the output of the photodetector **130** into, for example, a desirable form.

The time course variation in the detected signal associated with a cardiac vessel pulse at different wavelengths may be used to calculate the blood content, such as blood oxygen saturation, and other parameters associated with the cardiac vessel pulse. There are various ways to calculate blood oxygen saturation as a function of variations in the detected signal caused by cardiac vessel pulse at multiple light wavelengths, e.g. at 780 nm and 850 nm. As one of skill in the art will appreciate, the selected wavelengths for use in blood content determination will vary with the blood parameter being determined. For example, wavelengths of 690 nm and 830 nm, may be used to obtain deoxygenated haemoglobin and oxygenated haemoglobin content, respectively. A wavelength of 950 nm may be used to obtain water content of blood. Moreover, the blood parameter of interest may be determined through photon diffusion equations, photon transportation equations or Modified Beer Lambert's Law as will be described.

Modified Beer Lambert's Law

The detected signal (e.g. current) may be expressed as:

$$I_{\lambda_1} = I_{0,\lambda_1} e^{-B[\varepsilon_{Hb,\lambda_1}\cdot(C_{Hb}+\Delta C_{Hb})+\varepsilon_{HbO,\Delta_1}\cdot(C_{HbO}+\Delta C_{HbO})]L+\Lambda} \quad (1)$$

where:

I_{λ_1} is the signal provided by the photodetector at wavelength λ_1,

I_{0,λ_1} is the signal from the light source at wavelength, λ_1,

C_{Hb}, C_{HbO} are the concentrations of deoxygenated and oxygenated hemoglobin of steady tissue medium blood;

ΔC_{Hb}, ΔC_{HbO} are the changes in the concentrations of deoxygenated and oxygenated hemoglobin caused by the jugular vein pulse;

ϵ_{Hb,λ_1}, ϵ_{HbO,λ_1} are the absorption properties of deoxygenated and oxygenated hemoglobin at wavelength λ_1 for the purposes of calculating blood oxygen saturation. Blood saturation of other chromophores can also be calculated by substituting into the equation the appropriate extinction coefficients (ϵ) for the selected chromophore including, for example, water, cytochromes such as cytochrome oxides, and cholesterol; and

A. B are constants determined by boundary conditions.

The relative change in signal from the signal emitted from the light source to the signal detected by the photodetector which is caused by the jugular vein pulse is represented for a first wavelength by:

$$\Delta I_{\lambda_1} = e^{-B[\varepsilon_{Hb,\lambda_1}\cdot(\Delta C_{Hb})+\varepsilon_{HbO,\lambda_1}\cdot(\Delta C_{HbO})]L}; \quad (2)$$

or as

$$OD_{\lambda_1} = \ln(\Delta I_{\lambda_1}) = -B(\varepsilon_{Hb,\lambda_1}\cdot\Delta C_{Hb} + \varepsilon_{HbO,\lambda_1}\cdot\Delta C_{HbO}). \quad (3)$$

Similarly, the change in signal between emitted and detected signal for a second light wavelength is represented by:

$$OD_{\lambda_2} = \ln(\Delta I_{\lambda_2}) = -B(\varepsilon_{Hb,\lambda_2}\cdot\Delta C_{Hb} + \varepsilon_{HbO,\lambda_2}\cdot\Delta C_{HbO}). \quad (4)$$

Blood oxygenation derived from jugular vein pulse is then determined using the following equation:

$$S_{jv}O_2 = \frac{\Delta C_{HbO}}{\Delta C_{Hb}+\Delta C_{HbO}} = \frac{\varepsilon_{Hb,\lambda_1}\cdot OD_{\lambda_2} - \varepsilon_{Hb,\lambda_2}\cdot OD_{\lambda_1}}{(\varepsilon_{Hb,\lambda_1}-\varepsilon_{HbO,\lambda_1})\cdot OD_{\lambda_2} - (\varepsilon_{Hb,\lambda_2}-\varepsilon_{HbO,\lambda_2})\cdot OD_{\lambda_1}}. \quad (5)$$

In use, the patch probe **28** of device **10** comprising light source(s) **20** and photodetector(s) **30** is generally placed on the neck of the patient at a site near a selected blood vessel, for example, the internal jugular vein. It is desirable for the patient to be lying down at about a 30 degree incline from the horizontal. The patient maintains regular breathing during the process of measuring the pulse of the blood vessel. Light from the light source **20** is either reflected off of, or transmitted through, the target site on the patient's neck, and detected by the photodetector **30**. The photodetector **30** translates the detected light into an output signal (e.g. current/voltage) that may be digitized for expression as amplitude as a function of time to result in a waveform of the selected blood vessel pulse. The amplitude of signals obtained using different wavelengths may be used according to Lambert's law as above to determine blood oxygenation.

In another embodiment, illustrated in FIG. **9** (A-C), a device **200** is provided comprising one or more light sources **220**, each emitting selected wavelengths of light in the 400 nm to 1000 nm range. Each light source **220** is coupled with at least two photodetectors **230** each adapted to receive light emitted at a given frequency. As discussed above, the device **200** may optionally be incorporated within a system as illustrated in FIG. **5**, for example.

The device **200** is useful to simultaneously measure multiple cardiac blood vessel pulses, such as jugular venous pulse as well as carotid arterial pulse, thereby generating a dual waveform as illustrated in FIG. **10**, and thus, has utility to simultaneously measure arterial blood oxygenation, S_aO_2, in addition to central venous oxygenation, $S_{jv}O_2$, as described above. As one of skill in the art will appreciate, in the case of multiple light sources **220**, each light source is turned on in sequence, and the amplitude of light emitted from the light source(s) is modulated at a selected frequency, such as 10 kHz or 20 kHz. Alternatively, light emitted by a single light source **220** can be sequentially modulated at two alternating frequencies, such as 10 kHz and 20 kHz. The output from the photodetectors (e.g. current/voltage) is filtered at a frequency selected to correlate with a given frequency emitted from a light source, for example, using a band pass filter which allows a selected frequency, such as a 10 kHz or 20 kHz signal, to pass through but blocks other frequency components in the signal.

In another embodiment, cardiac output may be measured or monitored. As the jugular vein pulse represents central venous blood and correlates well with mixed venous blood, the trend of cardiac output can be calculated through Fick's Law as follows:

$$COI = \frac{OCR}{S_aO_2 - S_vO_2} \quad (6)$$

where COI is the cardiac output index which is the cardiac output (CO) per unit body surface;

OCR is the oxygen consumption rate which is oxygen consumption (OC) per unit body surface;

S_aO_2 is the arterial blood oxygen saturation; and

$S_{jv}O_2$ is the venous blood oxygen saturation.

S_aO_2 and $S_{jv}O_2$ may be determined as outlined above using a device in accordance with the invention.

The following equation depicts cardiac output (CO) as a whole rather than per unit body surface:

Or:

$$CO = \frac{OC}{S_aO_2 - S_{jv}O_2} \quad (7)$$

As the oxygen consumption or oxygen consumption rate are constant during many clinical procedures, the trend of cardiac output index or cardiac output can be reliably monitored.

In another embodiment, a method of measuring central venous pressure is provided. Central venous pressure is the pressure at the vena cava close to the right atrium. Abnormally high central venous pressure is an early indication of right atrial heart failure. Currently, central venous pressure is measured through invasive catheters which are inserted through the internal jugular vein to the vena cava.

A method for measuring central venous blood pressure in a patient is provided that is based on the fact that the length of blood filled inside a jugular vein directly reflects the central venous pressure. A determination of the highest position along the jugular vein where there is a pressure wave provides information that may be used to calculate venous blood pressure. Thus, the method comprises the step of determining the highest position along the jugular vein to yield a waveform. The "highest position" is measured from the sternal angle. The sternal angle is the angle formed by the junction of the manubrium and the body of the sternum in the form of a secondary cartilaginous joint (symphysis). This is also called the manubriosternal joint or Angle of Louis.

A waveform is obtained by directing a beam of light having a wavelength in the range of 400 nm to 1000 nm at an external tissue site on the patient that is in the proximity of the jugular vein, detecting light reflected from the tissue site or transmitted through the tissue site and translating the detected light into an output signal against time to generate a waveform. The highest position along the jugular vein to yield a waveform is determined when the next highest position does not yield a waveform.

The mean central venous pressure (P) is calculated as follows:

$$P=5+d\cdot\sin\theta$$

wherein d is the distance from the sternal angle to the highest position that yields a waveform. The addition of 5 to d represents the distance from the sternal angle to the right atrium. The symbol, θ, is the inclined angle of the upper body relative to the horizontal position.

Having obtained a waveform from a cardiac vein, the central blood pressure may be calculated as follows:

$$P = a + b\frac{T}{t}$$

wherein a is a constant that relates to the position of the sensor on the neck, and b is a constant which relates to the distance between the source and the photodetector of the sensor; and T is the pulse width and t is the average rise and fall time of the pulse.

In accordance with the method of measuring central venous pressure, a device **300** is provided. The device **300**, as shown in FIG. **13**, includes a series of light sources **320** located adjacent to one another along a length appropriate to measure the blood level in a cardiac vein, such as the internal or external jugular vein. The length will generally be about 1.5 to 10 cm. Each light source **320** emits light at a wavelength of from 600 nm to 900 nm and is associated with a corresponding photodetector **330** suitable to detect reflected or transmitted light from its corresponding light source **320**. The device **300** additionally includes a patch probe **328** that functions as the interface between the light sources (**320**) and photodetectors (**330**) and is adapted for placement on a patient at a site in the vicinity of a selected cardiac blood vessel, such as a cardiac vein. The probe **328** may incorporate the light sources **320** and photodetectors **330** directly, or may instead incorporate light transmitting optical fibres and light receiving optical fibres connected to the light sources and photodetectors, respectively, or may include a combination of these, e.g. light sources and light receiving optical fibres, or light-transmitting optical fibres and photodetectors. In addition, the device **300** may be incorporated within a system as previously described including a signal-processing device to translate the output of the photodetectors into a desirable form.

In use, the device **300** is placed on the patient at an appropriate site in which a terminal light source in the series is lined up with the sternal angle. The light from each light source is detected by its corresponding photodetector. The signal (e.g. current/voltage) of each photodetector is monitored (or transmitted to a signal processing device for translation to an alternate form of output such as a visual waveform output which is monitored) to determine whether there is an output or not. The highest position (d) along the vein to yield an output, e.g. a waveform, is then determined based on the output from each photodetector in the sequence. The mean central venous pressure (P) may then be calculated as described above.

FIG. **14** illustrates other embodiments of the device **300** that may also be useful to measure central venous pressure as described above. Each embodiment includes a different configuration of the light source(s) and photodetectors. For example, FIG. **14**A illustrates a device including a single light source and an array of adjacent photodetectors that may be used to obtain an output, e.g. a waveform, sequentially along a vein to determine the highest position (d). FIG. **14**B illustrates a device including sequential source-detector pairs in an alternating configuration (source-detector, source-detector, etc.) for placement along a vein as shown. FIG. **14**C illustrates a device similar to that of FIG. **14**B including multiple rows of alternating source-detector pairs. As one of skill in the art will appreciate, a device as shown in FIG. **1** may also be used to determine the highest position (d) along the vein to yield an output signal (e.g. a waveform) by obtaining waveform readings sequentially from the sternal angle upward along the vein. Further, as previously described, the device, regardless of its configuration may be incorporated within a system comprising a signal-processing device in order to translate the output of the photodetector into a visual output such as a pressure waveform.

The central venous pressure may also be determined utilizing pressure detection e.g. determination of a pressure waveform, as described above and an externally applied pressure. In this case, a pressure waveform is obtained, as described, and monitored via a display unit **44**. An external pressure is then applied to the selected venous vessel from the skin surface while monitoring the pressure waveform (representative of baseline pressure). The externally applied pressure is increased until the pressure waveform disappears as determined by monitoring the display unit. The central venous pressure P_c is then determined as follows:

$$P_c=P_{ef}-P_{ei}$$

wherein p_{ef}, is the value of the externally applied pressure at which the pressure waveform disappears and p_{ei}, is the value of pressure at which the pressure waveform starts to change (or the amplitude of the waveform starts to decrease).

A device comprising two light source-detector pairs, or two patches each comprising a light source-detector pair may be used in accordance with the foregoing method.

Central venous blood flow velocity may also be measured using a device in accordance with the present invention. By measuring the rise or fall time of a pressure waveform (t), or

the mean of the rise and fall time, the central venous blood flow can be calculated as follows:

$$v = \frac{d}{t}$$

wherein d is the spacing between the source and photodetector; and

t is the rise time of the pressure waveform (from the bottom to the peak).

The blood flow may be estimated according to:

$$F = v \times S$$

wherein S is the cross-sectional area of the blood vessel, which can be obtained through ultrasound imaging, and velocity (v) is determined as indicated above.

In a further embodiment of the present invention, a device corresponding to the device of FIG. **1** is provided which is adapted to generate an output from a cardiac vein remotely. Accordingly, the device comprises a remote light source capable of delivering a light beam to a desired site on a patient, e.g. a site on the neck of the patient in close proximity to a cardiac vessel; and a remote photodetector, such as a CCD camera adapted to receive light from the source which is reflected off of the patient at the desired site. As described, the photodetector generates an output signal (e.g. current/voltage) that may be processed by a signal-processing device to generate a visual output (e.g. waveform) for display on a display unit.

Embodiments of the present invention are described by reference to the following specific examples which are not to be construed as limiting.

EXAMPLE 1

Measurement of Venous Pulse in a Patient

The venous pulse of a human subject was obtained using a device as shown in FIG. **1**. The patient lay on a chair at about a 30 degree recline. The sensor patch of the device was placed on the neck of the patient at a site over the internal jugular vein. While the subject maintained normal breathing, venous pulse was measured and recorded. FIG. **12** illustrates the waveform recorded. The amplitude of the detected signal is represented along the y-axis while the x-axis represents time.

EXAMPLE 2

Measurement of Central Venous Pressure in a Patient

The central venous pressure of a human subject was obtained using a device as shown in FIG. **13**. The sensor patch of the device was placed on the neck of the patient at a site over the internal jugular vein such that the terminal source/detector of the device was at the sternal angle of the subject. While the subject maintained normal breathing, venous pressure was measured and recorded as a function of body position when the patient was lying flat (0 degree incline, e.g. horizontal), at a partial rise (45 degree incline from the horizontal) and sitting upright (90 degree incline from the horizontal) as shown in FIG. **15**A. The measured pressure as depicted by the waveform illustrated in FIG. **15**B is consistent with the expected central venous pressure in a healthy subject which decreases as body position rises from the horizontal position.

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I claim:

1. A system useful to determine central venous pressure in a patient comprising:

at least one light source adapted to emit light in the 400 nm to 1000 nm wavelength range;

an array of adjacent photodetectors adapted to sequentially receive light emitted by the light source and translate said light into a recordable output wherein said light is reflected from or transmitted through tissue of the patient, wherein the photodetectors are adjacent along a length of about 1.5 to 10 cm, and

at least one probe which facilitates delivery of light from the light source to an external tissue site on the patient in

the proximity of the jugular vein and receipt of light reflected from or transmitted through said patient site by the photodetectors;

a signal-processing device in communication with the photodetectors adapted to translate the output from said photodetectors to determine the highest position along the vein to yield a signal and calculate therefrom central venous pressure.

2. A system as defined in claim **1**, wherein the signal-processing device executes an algorithm that inverts the output from the photodetectors in order to reflect variations in blood volume or blood flow in the jugular vein and thereby yield a pressure waveform.

3. A system as defined in claim **1**, wherein said light source and said photodetectors are embedded in said probe.

4. A system as defined in claim **1**, comprising a plurality of light sources and a plurality of photodetectors, wherein each light source emits light that is received by a corresponding photodetector.

5. A system as defined in claim **1**, comprising a plurality of probes, wherein each probe comprises at least one light source and at least one photodetector.

6. A system as defined in claim **1**, wherein said probe is compatible for placement on the skin of a patient.

7. A system as defined in claim **1**, wherein said signal-processing device comprises a microprocessor and a display unit.

* * * * *

专利名称(译)	测量心脏功能参数的方法和装置		
公开(公告)号	US8417306	公开(公告)日	2013-04-09
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[标]申请(专利权)人(译)	程雪峰		
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IPC分类号	A61B5/00		
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其他公开文献	US20090326352A1		
外部链接	Espacenet USPTO		

摘要(译)

提供了一种用于非侵入地测量患者心脏血管的至少一个参数的装置。该装置包括至少一个发射400nm至1000nm波长范围的光的光源;至少一个光电探测器，适于接收由光源发射的光并基于所接收的光产生输出，其中所述光从患者的组织反射或透射通过患者的组织，所述光电探测器的输出与血液的参数相关联船只;和至少一个探针，用于促进光从光源传递到心脏血管附近的患者的外部组织部位和光电探测器接收光。还提供了利用该装置和/或系统监测/测量心脏参数的系统和方法。