Abstract: A device for measuring blood pressure, the device comprising: a laser (4) for directing coherent light onto a patient’s skin; a light receiver for receiving light scattered back from the patient’s body; a sensor comprising: a photodetector (6) for receiving light from the light receiver and creating a detector signal indicative of blood flow oscillation; and an indicator for indicating blood pressure at a predetermined level of blood flow oscillation. The device further comprises a pressure cuff for compressing a portion of a patient’s body. The sensor is preferably a laser Doppler sensor which measures microcirculatory blood flow in the patient’s skin.
This invention relates to a device for measuring and/or monitoring human or animal blood pressure, and to a method of measuring and/or monitoring blood pressure.

Blood pressure is a term used to describe arterial blood pressure, and is caused by the pumping action of the left ventricle of the heart, and the resistance of flow caused by the vascular system. When the heart beats, blood is forced through the arteries to the capillaries.

Blood pressure is typically characterised by two readings, the systolic and the diastolic pressures. The systolic pressure is the pressure as the heart contracts and is the higher of the two pressures. The diastolic pressure is the pressure when the heart relaxes and fills with blood in preparation for another contraction of the heart.

Blood pressure is one of the top three most common measurements made every day by clinicians. Significant decisions about the clinical management of patients and their medication are completed every day on the basis of blood pressure recordings. The most recent mass market analysis states that 33% of all adults suffer from high blood pressure (hypertension) (1). Blood pressure is a major contributor to morbidity and mortality around the globe. Approximately 30% of the adult population around the world suffer from hypertension (2).

Blood pressure measurement enables:

a) detection of hypertension
b) grading of the severity of the hypertension
c) monitoring the effects of lifestyle modification, diet and drugs
d) determining the transitional risk profile to the subject.
A wealth of new data, in each of the four areas, above has initiated an update of the guidelines for management of hypertension by the British Hypertension Society (3). These guidelines have evolved continuously as it has become apparent that medication can only have marginal incremental impact on health outcomes. In this context, accurate measurement of blood pressure is very important.

In addition, Life Assurance companies and Medical Insurance companies utilise blood pressure measurements to classify the risk to the health of their members. They are constantly seeking to improve the way they measure blood pressure and would readily entertain more accurate methods.

Hypertension prevalence varies by age, gender, race/ethnicity, socio-economic status, education and quality of healthcare and is summarised in the table shown in Figure 1.

This data provided the first estimates for rates of defined high blood pressure and its trend over time, being directly comparable for a range of different categories. However, such comparisons have several technical caveats that have to be taken into consideration such as the varying number of measures, techniques used and different operators.

Hypertension is the most important modifiable factor of cardiovascular, cerebrovascular and renal disease. Home blood monitoring using automated devices has become popular in clinical practice. However, it has also been shown that poor reporting accuracy of home blood pressure measurements is found, especially in less educated patients. In addition the 'white coat' effect in which a patient's blood pressure increases due to anxiety surrounding a medical consultation, shows that there are differences in readings taken by trained hypertensive patients performing their own readings, as well as those undertaken by clinical practitioners.
It is known to monitor blood pressure using a manual auscultatory method. Such a method typically uses a stethoscope and mercury manometer connected to an inflation device known as a sphygmanometer, and comprising a bladder.

When using a manual auscultatory method to measure blood pressure, a pressure cuff is typically secured around a limb of a patient. The cuff is inflated to a sufficiently high pressure to cut off, or occlude, arterial blood flow in a portion of the limb of the patient defined by the dimensions of the cuff. The cuff is then gradually deflated to allow the artery to slowly open. As the cuff is deflated, blood is again able to pass through the previously occluded artery.

As the blood is able to pass through the artery, sounds known as Korotkoff sounds are created. These sounds are indicative of blood pressure and can be detected by trained clinicians using a stethoscope to determine the person's blood pressure.

This known method involves palpation of the radial pulse in a wrist of a patient, the placing of a stethoscope on the brachial pulse, insufflating the sphygmanometer until the radial pulse disappears, and then auscultating the brachial artery for returning sounds, thereby determining the systolic and diastolic blood pressures.

A problem with this known method is that it can be laborious and can take several minutes to complete properly. In addition in order to obtain an accurate blood pressure measurement, the pressure cuff must be accurately positioned on a limb of the patient, usually the arm of the patient, such that the centre line of the cuff is in line with the patient's heart.

Another problem with this known method is that in the European Union, there has been a directive to reduce the use of mercury and also its release into the environment. As a result it is likely that the life-cycle of such devices in the future will be limited, in addition the manual auscultatory technique relies upon the skill of the operator and is not suitable for patient use.
Another known manual auscultatory method uses an aneroid device instead of a manometer.

A problem with this known method is that an aneroid device is made up of a delicate system of gears and bellows that can be easily damaged by rough handling. In addition an aneroid device "fatigues" with use and time, leading to inaccuracy. Current research suggests that at least 30% of these devices in use are out of calibration and the error almost always leads to readings that are too low (4, 5).

It is also known to use automated and semi-automated oscillometric devices to measure blood pressure. Such devices detect vibration or pressure oscillations of the arterial wall in order to allow blood pressure measurements to be taken.

In order to take a blood pressure measurement using an oscillometric device, a cuff is placed around a limb of a patient, usually an arm. The cuff is then inflated. During cuff inflation, the artery is occluded, and when pressure is released from the cuff, bloodflow resumes through the artery. This causes vibrations in the arterial wall, which are detected by a pressure transducer in the device. Pressure changes in the artery are recorded with every heartbeat and displayed as an oscillogram.

The oscillogram consists of two parts:

1. a pressure curve as the cuff inflates and deflates
2. oscillations/vibrations of the arterial wall.

The device then uses a mathematical formula (algorithm), which is unique to that specific device, to derive the blood pressure. The mean arterial pressure is usually equal to the cuff pressure at the point of maximum oscillation.

In oscillometric blood pressure systems, the amplitude of pressure oscillations in the blood pressure cuff is used to indicate the presence of arterial flow. At cuff pressures in excess of systolic blood pressure, the pressure oscillation amplitude is
As the cuff pressure is reduced to the systolic blood pressure, oscillation amplitude increases, and continues to do so as the cuff pressure is further decreased. When the cuff pressure is at the mean arterial pressure, the oscillations are at a maximum, and they decrease thereafter as the cuff pressure is further lowered. Commercial systems are calibrated so that diastolic, mean, and systolic blood pressure can be calculated from the oscillometric amplitude.

A problem associated with known oscillometric methods and devices is the somewhat arbitrary calibration that must be carried out to find the systolic and diastolic pressures from the waveform. This is because the pressure oscillations of the arterial wall persist at cuff pressures above systolic pressure and below diastolic pressure. Other limitations due to arterial stiffening, also affect the calibration process.

Automated devices including automated oscillometric devices described above, are however, known to be inaccurate, although more accurate devices are slowly coming onto the market (6). Several factors can influence the accuracy of an automated device. They include:

- Observer errors: Errors such as selecting the incorrect cuff size and/or not keeping the arm at heart level when a measurement is taken, can occur.
- Movement, arrhythmia or heart valve disease: If the patient moves during measurement or has a cardiac arrhythmia or heart valve disease, this leads to the device recording a distorted signal. This in turn leads to inaccurate analysis.
- Arterial disease: Patients with arterial disease such as SLE (Systemic Lupus Erhythmatois) or Raynaud’s syndrome have a decreased elasticity of the arterial wall. Restricted movement/vibration of the arterial wall causes a 'flattened' signal, which complicates analysis.
- High systolic or diastolic pressures: It is well known that automated devices are more inaccurate at higher pressures. This could be due to various factors including a higher resistance in the blood vessels.
Diastolic pressure measurement is particularly prone to error, mostly due to operator error (7, 8). As many treatments and therapeutic managements are prescribed on the basis of diastolic pressure (while recently systolic pressure has been given increasing clinical value) there is a clear need for more correct measurements.

Of the known methods and devices for measuring blood pressure, manual auscultatory methods and devices using mercury manometers are perceived to be the most accurate. However, such devices and methods have various disadvantages as set out above. One disadvantage is the use of mercury which has potentially harmful side effects. Another disadvantage is that since an operator must determine blood pressure using acoustic methods, there is an element of operator error in the blood pressure measurements.

A problem associated with oscillometric devices is that pressure of oscillations and occluded artery persist at cuff pressures above systolic, and also at cuff pressures below diastolic pressure.

According to a first aspect of the present invention there is provided a device for measuring blood pressure, the device comprising:

- a laser for directing coherent light onto a patient's skin;
- a light receiver for receiving light scattered back from the patient's body;
- a sensor comprising: a photodetector for receiving light from the light receiver and creating a detector signal indicative of blood flow oscillation;
- and

an indicator for indicating blood pressure at a predetermined level of blood flow oscillation.

Advantageously the device further comprises a pressure cuff for compressing a portion of a patient's body.
The photodetector is adapted to create a detector signal indicative of either microcirculatory or arterial flow oscillation. The indicator indicates either arterial or microcirculatory pressure at a predetermined level of blood flow oscillation.

Preferably however, the photodetector is adapted to create a detector signal indicative of microcirculatory flow oscillation, and the indicator is adapted to indicate arterial blood pressure at a predetermined level of microcirculatory flow oscillation.

The photodetector may be adapted to measure both microcirculatory, and arterial flow oscillation.

In use, the pressure cuff would be positioned around a limb of a patient and inflated in a known manner to a pressure above systolic pressure.

The pressure oscillations in the microvascular circulation, in other words the capillaries and arterioles, are arrested at cuff pressures over systolic, as long as the laser is positioned to direct coherent light onto a patient's skin at a point downstream of the pressure cuff. The point at which the light contacts the patient's skin is known as the laser launch point.

The terms "upstream" and "downstream" are used herein to described positions around a circulatory system of a patient. In other words, if the laser launch point is downstream of the pressure cuff, when the pressure cuff is inflated to a pressure above systolic, the flow of blood downstream of the cuff will be effectively blocked by the pressure applied by the pressure cuff, and therefore flow oscillations detected by the photodetector will be substantially arrested at laser launch point.

The device according to the present invention retains the advantages of the auscultatory method in that the device measures actual blood flow to obtain a signal indicative of the blood pressure, rather than using a surrogate measurement.
In addition, the device according to the present invention is relatively simple to use and easily portable.

By means of the present invention, the systolic pressure of a patient can be readily determined without calibration since this pressure is concurrent with the onset of microcirculatory oscillations. In other words, as the pressure in the cuff is reduced in a known manner, microcirculatory flow oscillations will gradually be detectable. As with existing auscultatory methods, the first detectable signal of microcirculatory flow oscillations detected through use of a device according to a first aspect of the present invention, is used to identify the systolic pressure of the patient.

Curve tracings may be generated in an experimental settings by taking measurements on normal subjects, to show how flow oscillations will vary as the cuff pressure is reduced. Interpretation of such curve tracings provides systolic, diastolic and means pressure readings.

A device according to the first aspect of the present invention could also be calibrated using a indwelling catheter. Such calibration would not be continuous calibration, but calibration post-production of the device. In addition, interval calibration as a system quality check could also be carried out.

By means of the present invention, an artery in a patient may be compressed by means of the pressure cuff, and arterial flow oscillation may subsequently be measured, thereby obtaining data corresponding to arterial blood pressure.

By means of the present invention it is possible to detect oscillations in the microvascular circulation of a patient and to then relate these oscillations to systolic and diastolic pressure.

The inventors have realised that flow oscillations in the microvascular circulation of a patient (i.e., in the capillaries and arterioles) are substantially completely arrested at cuff pressures above systolic. This means that the systolic pressure can
be readily determined without calibration because it is concurrent with the onset of microcirculatory oscillations.

Preferably the laser comprises a diode (semi-conductor) type laser. Advantageously the laser operates at a single frequency, continuous power and at a wavelength between 600 and 1200 nanometers.

Wavelength outside the range 600 to 1200 nanometers may be used.

Advantageously, the laser has maximum spectral width of 0.1 nanometers when the wavelength falls between 600 and 1200 nanometers.

Preferably, the laser would operate at a single frequency. As the laser frequency bandwidth increases, the signal quality decreases. This means therefore, that if the laser is not truly a single frequency laser, then the maximum bandwidth is preferably 0.1 nanometers. However, in certain circumstances lasers having a wider spectral width may also be appropriate for use in forming part of the present invention.

Conveniently, the output power of the laser is in the range of 0.5 to 2 milliwatts and preferably the output is greater than 1 milliwatt.

The laser output may be higher than 2 milliwatts under certain circumstances, although current safety limits indicate that the output of the laser should be no more than 2 milliwatts.

If the laser power falls to below 0.5 milliwatts, the output signal is weak and the signal to noise ratio is poor.

Any suitable lasers however, may be used such as helium neon gas lasers, providing such lasers have modal stability (i.e., single frequency).
It may be necessary to generate an oscillator signal whilst measuring blood pressure using a device according to the present invention, at elevated heart rates of up to 120 or 150 beats per minute. In such circumstances it will be necessary to measure blood pressure between 1500 and 2000 times a minute.

The reproducibility of the blood flow measurement is a function of the time allowed per measurement. It is therefore advantageous to optimise the signal to noise ratio.

Each flow measurement is generated as a digitised independent measurement, although analogue systems could also be used.

Advantageously, the photodetector comprises a PIN type photodetector having high sensitivity and low noise specifications.

Preferably, the device further comprises a housing for housing the sensor, which housing prevents or reduces contamination of low level photo current signal by surrounding an electromagnetic field.

In other embodiments, the laser and/or the indicator may also be received within the housing.

The housing may be formed separately to the pressure cuff. The housing, containing the sensor may be positioned at a point downstream of the portion of the body of the patient to which the pressure cuff has been applied.

The pressure cuff may be applied to any appropriate portion of a patient such as an arm, leg, finger or toe.

In embodiments of the invention not including a housing, the sensor will be positioned at a point distal to the heart of the patient compared to the position of the pressure cuff.
In embodiments of the invention, the laser light is directed onto a portion of the skin of the patient, preferably at a location slightly distal to the pressure cuff. The laser light will, therefore, enter the body of the patient at a point downstream of the point at which pressure is applied to the body of the patient. This means that, for example, when maximum pressure is applied to the body of the patient via the pressure cuff, the microcirculatory pressure oscillation at a point slightly distal to the cuff will be substantially completely occluded.

Advantageously, the device further comprises a preamplifier having low noise characteristics, which preamplifier filters and amplifies the output of the photodetector.

Conveniently, the device further comprises a laser driver, which laser driver provides a controllable drive current to operate the laser in a stable manner, and prevent current transients that could damage the laser.

Tests are inconclusive as to whether any damage produced in patients due to hypertension is associated only with systolic and diastolic components, or whether it is also associated with altered perfusion in the microvascular circulation of a patient. It is believed that perfusional measurements will enable identification of patients who are at higher risk of having problems associated with hypertension. This will enable more aggressive selective treatments to be applied to such patients in order attempt to reduce any such problems.

The perfusional value, the amplitude of volume changes, the duration of systolic and diastolic waves, the values at arteriolar level, or pulsatile flow, and the real perfusional non-pulsatile flow which is the characteristic of the capillary system of a person, may all be measured using a device according to the present invention. Such measurements may offer a new insight into diseases such as hypertension.

The device according to the first aspect of the present invention can also be used to obtain arteriolar (terminal pulsatile pressure) and perfusional (non-pulsatile, continuous, capillary pressure).
According to a second aspect of the present invention there is provided a method of measuring blood pressure comprising the steps of:

- applying pressure to a portion of a patient's body;
- applying a coherent light to the skin of the patient downstream from the portion of the body to which pressure is applied;
- receiving light scattered back from the skin of the patient;
- processing the received light to create a signal indicative of a level of blood flow oscillation in the patient;
- determining the arterial blood pressure of the patient at a predetermined level of blood flow oscillation.

Preferably, the pressure is applied using a pressure cuff applied to an appropriate portion of a limb of a patient.

Advantageously, the coherent light is launched into the skin of a patient at a point downstream of the pressure cuff.

Advantageously, the step of processing the received light creates a signal indicative of microcirculatory blood flow oscillation.

Alternatively, the step of processing the received light creates a signal indicative of arterial blood flow oscillation.

Preferably, the method further comprises the steps of insufflating the pressure cuff to a pressure above systolic blood pressure;

- reducing pressure in a predetermined manner;
- identifying the blood pressure at which a first signal is detected;
- determining the patient's systolic pressure from the first signal that is detected;
- detecting further signals as the pressure cuff is deflated, and determining blood pressure corresponding to these further signals.
Advantageously, the blood pressure of a patient at various states of inflation of the pressure cuff is determined using one or more algorithms.

Advantageously, the pressure cuff is deflated at a rate of substantially 2 mmHg.

References

1. Time Magazine 13th December 2004


The invention will now be further described by way of example only with reference to the accompanying drawings in which:

Figure 1 illustrates a table showing the prevalence of hypertension in 15 selected countries;

Figure 2 is a schematic representation of a device for monitoring blood pressure according to a first aspect of the present invention;
Figure 3 is a schematic representation showing positioning of a pressure cuff and Laser Doppler module forming part of a device according to an embodiment of the first aspect of the present invention;

Figure 4 is a more detailed schematic representation of the device of Figure 2;

Figure 5 is a schematic representation of a second embodiment of a device according to the first aspect of the present invention including a plug for a telephone or computer; and

Figure 6 is a schematic representation of yet another embodiment of a device according to the present invention in which the sensor is positioned close to a pressure cuff applied to the arm of a patient.

Referring to Figures 2 to 6, an embodiment of a device according to a first aspect of the present invention for measuring blood pressure is designated generally by the reference numeral 2. The device comprises a laser 4 for focussing coherent light 20 onto the skin of a patient whose blood pressure is to be measured or monitored. The light is launched into the patient at a laser launch point 21. The device further comprises a photodetector 6 and a light receiver 7, and which receive light 23 scattered back from the arm 30. The light receiver and photodetector together form a sensor 25 which is positioned to be in contact with the skin of the patient.

In order to measure the blood pressure of a patient using the device 4, a pressure cuff 8 of suitable size is placed around a limb of the patient, and in this embodiment, the cuff 8 is placed around the arm 30 of a patient at an area where the measurement is to take place. Standardised cuff widths and lengths have been established for limbs of various circumference.

Typically, the area of measurement will be the upper arm midway between the elbow and the shoulder as shown in Figure 3. Other regions of the upper and lower extremities may also be used, with the exception of joint areas such as the elbow, knee, wrist etc.
The device 2 comprises a pressure transducer forming part of the cuff operably
connected to an indicator display for indicating blood pressure at a particular level
of microcirculatory flow oscillation.

The laser 4 is positioned so that light 20 from the laser launch point is slightly
distal to the cuff relative to the heart of the patient.

The light from the laser is monochromatic or near monochromatic and has a
maximum spectral for width of 0.1 nanometers at a wavelength of between 600 to
1200 nanometers.

In the illustrated embodiments of the invention, the output of the laser is a range of
0.5 to 2 milliwatts and is preferably greater than 1 milliwatt.

Once light has been focussed from the laser onto the skin of the patient, the light
will enter the patient and will be scattered in the tissue. Most of the photons of
light will eventually pass through the limb, but a fraction of the light will reermerge from the skin near the point of entry. Some of these photons will have
suffered collisions with moving red blood cells in the skin and underlying tissue
microvasculature. Each collision, properly termed a "scattering event", imparts a
small frequency change (the "Doppler frequency") to the photon. The magnitude
of this frequency change is generally less than a few hundred Hertz in skin using
commercially available laser Doppler blood flow systems. The magnitude of the
frequency change is a function of several random variables, including the speed of
a red cell and its direction of motion relative to that of the photon. Therefore a
range of Doppler frequencies will be present in the reemerging light.

The light receiver is in the form of, for example a microlens 10 which is placed at
a point radially separate from the laser launch point. Typically the microlens 10 is
positioned 0.5 to 1 mm away from the laser launch point.

In an alternative embodiment the light receiver may comprise an optical fibre.
The microlens 10 collects at least some of the reemerging light 23 that has been scattered within the tissue of the patient. TMs scattered light is transmitted to the photodetector 6. The photodetector may be any convenient type of photodetector, but is preferably a PIN photodiode or similar device.

The output of the photodetector 6 is in the form of a photocurrent that can be spectrally analysed to provide a measurement of the presence and magnitude of local blood flow in capillaries and arterioles in the skin of the patient.

As shown particularly in Figure 3, the sensor 25 may be contained within a housing which housing can prevent contamination of low level photocurrent signal produced by the photodetector 6 by surrounding electromagnetic fields.

The sensor 25 functions as a laser Doppler sensor which can measure local blood flow in capillaries and arterioles to a depth of approximately 1 to 2 mm in the skin. This means that the sensor 25 does not directly detect the presence of arterial flow. Instead the sensor 25 measures the blood flow in the microvasculature "downstream" of the arteries.

The inventors have realised that the blood flow in the microvasculature (or in the skin) necessarily depends on the blood flow in the upstream artery, and that therefore measurement of the blood flow in the microvasculature can be used to determine arterial blood pressure.

The terms "upstream" and "downstream" are used herein to describe the position of the device 2 relative to the pressure cuff and the heart of a patient.

The arterial flow is normally pulsatile, unless arrested by the pressure cuff 8 when inflated above systolic pressure. Microvascular flow is similarly pulsatile, albeit with some damping that is a consequence of the resistance of the smaller vessels.

The inventors have shown that the pulsatile (oscillation) amplitude in the microvasculature as measured by the sensor 25 is a predictable function of the
pressure of the cuff 8 and its relation to the systolic, mean and diastolic blood pressures.

The device 2 according to an embodiment of the first aspect of the present invention can therefore be calibrated to provide, using an appropriate algorithm, various blood pressure indices in an accurate and reproducible manner.

In the illustrated embodiment of the invention, the sensor 25 is mounted on the skin of a patient at a position close to, and downstream of, the pressure cuff 8.

The sensor 25 must be in intimate contact with the skin of a patient. The positioning of the sensor 25 may be accomplished by use of a material that clings naturally to the skin surface. Alternatively the sensor 25 may be secured onto the skin of a person using a disposable adhesive tape or similar means.

The blood pressure cuff 8 comprises a standard size blood pressure cuff which is used for encircling the limb (in this example the arm 30). When inflated the blood pressure cuff 8 applies pressure to compress an artery positioned within the body of the patient that is surrounded by the cuff 8. The cuff may be modified to provide for attachment of the device 2 to it.

Turning now to Figures 4 and 5, the device 2 will be described in more detail. The device 2 further comprises an inflation pump 40 which is used to inflate the pressure cuff 8. The inflation pump is connected to the cuff 8 by means of a pneumatic hose 42. The pump is of the type used on known automatic blood pressure monitors, and is capable of inflating the cuff to 200mm Hg within a few seconds, and is controlled by a pressure control module.

The pressure control module is controlled by the user of the device through a pressure control module 46.

On command, the pressure control module 46 operates the pump 40 to inflate the cuff 8 to a predetermined pressure. The starting pressure of the cuff will be set at
above systolic pressure of the patient. When the user operates the pressure control module 46 to begin deflation of the cuff 8, the module 46 deflates the cuff at a rate of approximately 2mm Hg per second.

When the blood pressure measurement has been completed, the user may activate the pressure control module 46 so that the module 46 completely deflates the cuff. The pressure sensor provides a signal to indicate the cuff pressure.

The pressure control module 46 may be powered by a battery or by a mains voltage. In the illustrated embodiments, the module 46 is powered from a mains voltage and is connected to the mains voltage by means of a power cable 47. The module 47 comprises an AC-DC converter in order that the module may be powered from a DC voltage.

The device 2 also includes a signal processor 48 with computation algorithms. The signal process accepts preamplified and prefiltered blood flow signal from the device 2 which signal will be in the form of a Doppler signal. This signal is broadband with an upper frequency limit of typically 5 KHz or less.

The signal processor carries out the following functions:

i. Final filtering and amplification of the Doppler signal.

ii. Application of an algorithm to correct for signal noise and calculate the microcirculatory blood flow. This step is performed at least 10 times per second, and preferably 20-30 times per second, in order to track oscillatory changes in blood flow during the cardiac cycle. This function may be performed by a digital signal processor or, alternatively, by an analog processing scheme at lower cost and lower precision.

iii Determination of the presence of blood flow (i.e., first non-zero flow measurement to occur as the cuff deflation occurs).

iv. Calculation of the cuff pressure based on a signal from the pressure transducer forming part of the cuff.
v. Tracking the oscillation amplitude of the blood flow (based on the real-time measurements) as a function of the cuff pressure.

vi. Application of a second algorithm that calculates the systolic, diastolic, and mean arterial pressures based on the relationship between the oscillation amplitude and the cuff pressure.

vii. Output of information to the user interface for display.

viii. Output of information to an external appliance (e.g., computer, modem) via the electrical connector.

The device further comprises a user interface including a minimum number of controls for ease of use. The interface preferably comprises push button switches for control of the system operation, including controls for power on/off and for the start of the test. The user interface further comprises an indicator in the form of, for example, a liquid crystal display for indicating the blood pressure information together with other relevant system status information such as the level of power in the battery (when the device is run from a battery or batteries), error messages etc.

Other forms of display may also be used, for example an LED display could also be used.

The device further comprises a data transfer connection which will enable transfer of blood pressure results to either a local computer or to a remote computer via a telephone connection. A standardised connector and transfer protocol will be used such as Firewire, USB etc.
CLAIMS

1. A device for measuring blood pressure, the device comprising:
   a laser for directing coherent light onto a patient's skin;
   a light receiver for receiving light scattered back from the patient's body;
   a sensor comprising: a photodetector for receiving light from the light receiver and creating a detector signal indicative of blood flow oscillation; and
   an indicator for indicating blood pressure at a predetermined level of blood flow oscillation.

2. A device according to Claim 1 further comprising a pressure cuff for compressing a portion of a patient's body.

3. A device according to Claim 1 or Claim 2, wherein the photodetector is adapted to create a detector signal indicative of microcirculatory flow oscillation.

4. A device according to any one of the preceding claims, wherein the indicator indicates arterial blood pressure at a particular microcirculatory flow pressure.

5. A device according to any one of the preceding claims, wherein the laser comprises a semiconductor diode type laser.

6. A device according to any one of the preceding claims, wherein the laser has a maximum spectral width of 0.1 nanometers and a wavelength between 600 and 1200 nanometers.

7. A device according to any one of the preceding claims, wherein the output power of the laser is in the range of 0.5 to 2 milliwatts.
8. A device according to any one of the preceding claims, wherein the photodetector comprises a PIN type photodetector.

9. A device according to any one of the preceding claims, further comprising a housing for housing the sensor.

10. A device according to any one of the preceding claims, further comprising a preamplifier.

11. A method of measuring blood pressure comprising the steps of:
    applying pressure to a portion of a patient's body;
    applying coherent light to the skin of the patient downstream from the portion of the body to which pressure is applied;
    receiving light scattered back from the skin of the patient;
    processing the received light to create a signal indicative of a level of blood flow oscillation in the patient;
    determining the arterial blood pressure of the patient at a predetermined level of blood flow oscillation.

12. A method according to Claim 11, wherein the pressure is applied using a pressure cuff.

13. A method according to Claim 11 or Claim 12, wherein the coherent light is launched into the skin of the patient at a point downstream of the pressure cuff.

14. A method according to any one of Claims 11 to 13, wherein the step of processing the received light creates a signal indicative of microcirculatory blood flow oscillation.

15. A method according to any one of Claims 12 to 14 further comprising the steps of insufflating the pressure cuff to a pressure above systolic blood pressure; reducing the pressure in a predetermined manner; identifying the blood pressure at which a first signal is detected;
determining the patient's systolic blood pressure from the first signal
detecting further signals as the pressure cuff is deflated, and determining
blood pressure corresponding to these further signals.

16. A device substantially as hereinbefore described with reference to the
accompanying drawings.

17. A method substantially as hereinbefore described with reference to the
accompanying drawings.
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**FIGURE 1**
FIGURE 3

- Pneumatic line
- Blood pressure cuff
- Laser Doppler module
FIGURE 4
FIGURE 6
INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2006/002944

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/0225

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)
A61B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category*</th>
<th>Citation of document, with Indication where appropriate of the relevant passages</th>
<th>Relevant to claim No</th>
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[Box C continued]

'X' Further documents are listed in the continuation of Box C

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 document but published on or after the international filing date
  'L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
  'O' document referring to an oral disclosure use, exhibition or other means
  'P' document published prior to the international filing date but later than the priority date claimed
  'T' later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
  'X' document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step 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
  'Z' document member of the same patent family

Date of the actual completion of the international search
6 November 2006

Date of mailing of the international search report
20/11/2006

Name and mailing address of the ISA/
European Patent Office, P B 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel (+31-70) 340-2040, Tx 31 651 epo nl,
Fax (+31-70) 340-3016

Authorized officer
Wöllinger, Martin

Form PCT/ISA/210 (second sheet) (April 2005)
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<td>DE 100 33 171 Al (ELTER PETER [DE]; LUTTER NORBERT [DE]; MUELLER GLASER KLAUS D [DE]; ST) 17 January 2002 (2002-01-17) paragraphs [0037] - [0039], [0041], [0044] - [0046] paragraphs [0052] - [0057] figures 4, 5, 8, 10, 11, 13</td>
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<td>UBBINK D TH: &quot;Toe blood pressure measurements in patients suspected of leg ischaemia: a new laser Doppler device compared with photoplethysmography.&quot; EUROPEAN JOURNAL OF VASCULAR AND ENDOVASCULAR SURGERY: THE OFFICIAL JOURNAL OF THE EUROPEAN SOCIETY FOR VASCULAR SURGERY. JUN 2004, vol. 27, no. 6, June 2004 (2004-06), pages 629-634, XP002405630 ISSN: 1078-5884 page 629, right-hand column, paragraph 2 - page 630, left-hand column, paragraph 1 page 630, left-hand column, last paragraph - right-hand column, paragraph 1</td>
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<td>A</td>
<td>EP 0 298 620 A (BOC GROUP INC [US]) 11 January 1989 (1989-01-11) column 5, line 10 - column 6, line 27 column 12, line 3 - column 14, line 32 figure 1</td>
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### DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>WO 99/39634 A (ABP TEK LTD [IL]; NITZAN MEIR [IL]) 12 August 1999 (1999-08-12) page 3, lines 18-26 page 5, line 21 - page 6, line 8 page 9, lines 7-29 page 10, line 29 - page 14, line 3 figure 4</td>
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INTERNATIONAL SEARCH REPORT

Box 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 16, 17 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
     
     see FURTHER INFORMATION sheet PCT/ISA/210

3. 
   - Claims Nos because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 64(a)

Box 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:

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 an additional fee this Authority did not invite payment of any additional fee.

3. As only some of the required additional search fees were timely paid by the applicant this International Search Report

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

Remark on Protest

- The additional search fees were accompanied by the applicant’s protest
- No protest accompanied the payment of additional search fees
Continuation of Box II.2

Claims Nos.: 16,17

Claims 16 and 17 do not define the subject-matter in terms of technical features as required by Rule 6.3(a) PCT. Instead, they merely refer to the accompanying drawing, contrary to Rule 6.2(a) 2nd sentence PCT.
<table>
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<td>US 5676140 A</td>
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