A DEVICE FOR EVALUATING BLOOD SYSTEM PROPERTIES

FIELD OF THE INVENTION

The present invention relates to the field of medical diagnostics. Specifically, the invention relates to devices and methods for the assessment of physiological properties of the circulatory blood system of the body.

BACKGROUND OF THE INVENTION

Blood pressure is a measurable parameter of the circulatory system of the body which can contribute significantly to the knowledge of the overall physiological condition of the body. In US Patent 3,980,075, a method is described for constantly monitoring and measuring tissue perfusion of the blood. Such a perfusion is dependent upon blood pressure and therefore can be used as an indication of the blood circulation in the target organ.

Physiological aspects of the blood pressure are many, since the factors effecting the blood pressure are numerous and blood circulation is involved in all functions of the body.

Reference is now made to Fig. 1, which is a graph schematically indicating the cyclic relationship between time and the amount of blood present in a specific cross section of an organ as measured by absorption of light at appropriate wave lengths. Graph B represents an organ or tissue which is more distal from the heart as compared to the organ of graph A . It is evident that there are not only small phase differences in the rhythmic changes of the blood quantity, but that the amplitude of the rhythm in the organ measured at the site

represented by graph B is different than the amplitude of the rhythm in the organ at the site of A.

SUMMARY OF THE INVENTION

An object of the present invention is to provide a detecting device for monitoring properties of circulating blood elements in a body. Such a device consists of at least one light sensor unit, consisting of at least one transmitter and at least one detector. The transmitter has a means for illuminating in at least one spectral component of continuous or pulsed light. The device also contains a controller for managing the light sensor and for determining the travel time of the light components.

A further object of the present invention is to provide a method for monitoring properties of the blood circulation system in a tissue by measuring at least in two different sites in the body the attenuation of light. According to the method the following steps are carried out: illuminating a tissue by light energy, detecting a portion of the light energy after being affected by the tissue, determining the attenuation of the light energy; determining the travel time of the light energy; and relating the attenuation and the travel time to at least one property of the tissue.

There is thus provided, in accordance with a preferred embodiment of the present invention, a device for detecting and monitoring the properties of circulating blood elements in a body. The device includes at least one transmitter for transmitting light through a tissue containing the blood elements with at least one spectral component of light, at least one detector for detecting at least a portion of the light transmitted through the tissue, a controller connected to the at least one detector and the transmitter, the controller controlling the transmitted light and determining the travel time of the transmitted light and a processing unit

connected to the controller, wherein the processing unit processes medical and physiological information about the tissue.

Furthermore, in accordance with a preferred embodiment of the present invention, the transmitter includes means for emitting at least one pulse of illumination, each of the pulses of illumination having at least one spectral component of light. The pulses may have similar magnitude proportional to their corresponding energy level or may be equally spaced apart. The pulses may include Direct Current (DC) light components.

Furthermore, in accordance with a preferred embodiment of the present invention, there are two detectors arranged in parallel.

There is also provided, in accordance with a preferred embodiment of the present invention, a method for monitoring properties of the blood circulation system in a tissue. The method includes the steps of:

transmitting light energy at the tissue,

detecting the light energy after having been affected by the tissue,

determining at least one property of the tissue.

Furthermore, in accordance with a preferred embodiment of the present invention, the step of determining the at least one property includes the steps of:

determining the attenuation of the light energy;

calculating the time for the light energy from transmission to detection; and

relating the attenuation and the travel time to the at least one property.

The light energy may be in the form of bursts containing spaced pulses, each of the spaced pulses having at least one spectral band.

Furthermore, in accordance with a preferred embodiment of the present invention, the step of determining includes the step of calibrating the static blood pressure at least two pre-determined points. At least one of the pre-determined points has a static blood pressure value of zero or an equivalent hydrostatic column of blood pressure value of zero or any other value.

Furthermore, in accordance with a preferred embodiment of the present invention, the step of determining includes the step of normalization, the normalization including the steps of:

processing the received signal at one or more measurement points to obtain a waveform; and

determining the time lag of the waveform, thereby to determine the group delay and viscosity.

The properties being determined include one of a group including circulatory system parameters at the cellular and sub-cellular level, systolic pressure, diastolic pressure, blood viscosity, change in viscosity, cardiac output, saturation of oxygen and systolic waveform and blood flow.

Alternatively, in accordance with a preferred embodiment of the present invention, the step of determining includes the step of measuring the blood circulation at different depths.

Furthermore, in accordance with a preferred embodiment of the present invention, the step of detecting includes the step of detecting light transmitted through or reflected by the tissue.

Furthermore, in accordance with a preferred embodiment of the present invention, the step of detecting includes the step of detecting the change in

frequency of reflected pulses received, thereby to determine the blood velocity. Also, the step of detecting includes the flow character.

Furthermore, in accordance with a preferred embodiment of the present invention, the method further includes the step of displaying at least one of the properties in at least one of group of formats including two-dimensional and three-dimensional form.

Additionally, in accordance with a preferred embodiment of the present invention, the also includes bio-feedback by changing the physiological status of the body thereby to alter the input of medical and physiological information about the tissue to the processing unit.

Finally, the light is transmitted via one of a group of sources including semi-conductor light emitting diodes (LED) and diode lasers.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the appended drawings in which:

Fig. 1 is a graphical description of the amount of blood present within two different tissues along a time axis;

Fig. 2A is a schematic illustration of a basic sensing unit according the invention;

Fig. 2B is a schematic illustration of the unit of Fig.2A with a spectral filter fitted in front of the transmitter;

Fig. 3 is a schematic illustration of the burst of pulses issued from a sensing unit;

Fig. 4 is a schematic illustration of a transmitted burst containing compound pulses;

Fig. 5 is a schematic illustration of two reference points for mean hydrostatic blood pressure in the human body, in which the one at the neck region is the zero mmHg;

Fig. 6 is a schematic illustration of a detector assembly for evaluating in depth variations in blood properties; and

Fig. 7 is a schematic illustration of bursts modulated by a superimposed energy wave.

DETAILED DESCRIPTION OF THE PRESENT INVENTION

In accordance with a preferred embodiment of the present invention, the dynamic change in the amount of blood in a specific tissue is recorded to assess the properties of the blood circulation and other tissue properties at the specific site. Properties of the circulation system as a whole can also be deduced from localized measurements as will be described later on. According to the present invention, the intensity of the light beam impinging upon a tissue is measured and the intensity of the light beam after being affected by the tissue is also measured, such that the effect on the tissue at a specific wavelength is measured. Thus, the more blood present at a specific site, the higher the effect in the visible and near infrared wavelengths.

A sensor unit, according to the present invention, comprises at least one transmitter and one detector of light. In its simplest form, as can be seen in Fig. 2A, to which reference is now made, a transmitter 12 illuminates a tissue 14. Some of the light is transmitted through the tissue, of which a portion is detected by a detector 16, and quantified and processed in a processing unit 24 for the extraction of medical and physiological information. A controller unit 22 is interposed between the processor 24 on the one hand and the detector 16 and transmitter 12 on the other hand. Alternatively, as is indicated by arrow 25, detector 17 can be set up to determine the reflected light from the tissue, rather than the transmitted light.

The source of light may include any suitable source such a semi-conductor light emitting diodes (LED) and diode lasers, as well as gaseous lasers such as Argon, Nd:YAG, Robedium and CO_2.

The controller 22 controls the light from the sensor unit and determines the travel time of the transmitted or reflected light. The controller can be connected to a display screen for purposes of displaying the results, such as for the purposes of bio -feedback training.

Fig. 2B, to which reference is now made, is a schematic description of an alternative sensor unit according to the invention in which a light filter 18 is added in front of transmitter 12 in order to enhance the spectral band selectivity of the device.

According to the invention, pulses of light can be utilized. The transmitter 12 can emit bursts as shown in Fig. 3 to which reference is now made, of spectrally identical light pulses. Burst A, burst B and burst C, typically each 500 microseconds long, which represent chains of bursts produced by the transmitter, are sent sequentially at identical intervals by the transmitter. In all the bursts, each pulse of light (31, 32, 33, 34, 35, 36, 37 etc.), typically 50 microseconds long, has an identical magnitude proportional to its energy level, meaning that all the pulses are identical energetically.

In a different embodiment, illustrated in Fig. 4 to which reference is now made, each burst of light, such as burst D, contains pulses such as pulses referenced 51 and 52. Each pulse is composed of a number of different spectral bands components, 58, 59 and 60, each having a magnitude proportional to their energy level at the specific spectral band. The passage of the pulses through issue 14 attenuates the energy level of the pulse, as marked by the lower magnitudes of detected pulses 61 and 62. The spectral components of each pulse, such as components 65, 66 and 67 may be attenuated differently. A

specific spectral attenuation pattern may be considered to have significance to specific physiological properties.

According to the Doppler effect, the apparent frequency of light pulses detected by the detector depends upon the speed in which the reflected bursts are moving. The pulses are aimed at the blood stream and their received frequency is affected by the speed of the blood stream. Therefore, by assessing the frequency of light pulses in the bursts, the radial velocity of the blood stream may be inferred. Fourier Transform analysis or wavelet analysis may be applied to the received light in order to extract the frequencies that make up the overall rhythm of the flow, thereby increasing the sensitivity to small differences in frequency, such that low liquid velocities can be calculated, such as within the range of 1cm/sec to 50cm/sec. Using the frequency analysis techniques, turbulent flow can be resolved into the composing frequencies, from which the laminar components can be extracted.

According to Poiseuille's law,

$$Q = \frac{\pi \Delta p r^4}{8 \eta l}$$

in which, Q = rate of blood flow

Δp = pressure difference along a vessel; r =vessel radius

l = vessel length;

η = viscosity

In order to extract the viscosity η, the variables Q, Δp, r, l, for a given length of a vessel are substituted by measured or otherwise known data. Blood

viscosity is a feature of the blood system that can be of great importance for assessing various physiological and medical conditions.

Calibration of measurements with respect to blood pressure

In order to establish the function between the measured parameters according to the embodiments of the present invention, and the blood pressure as measured by conventional means, a calibration step has to be performed. Textbook of Medical Physiology, 8th edition, Guyton, A.C. W.B. Saunders Company, pages 165 and 167 disclose the map of hydrostatic pressures in different locations along the venous system. The Applicant has realized that this map may also be used for artery system.

Reference is now made to Fig. 5, which is schematic illustration of hydrostatic blood pressure in the human body. The terms 'hydrostatic blood pressure' and 'static blood pressure' are used interchangeably herein. In Fig. 5, in the neck region 80, the venous pressure is reduced to zero. It is actively kept so by physiological feedback mechanisms, so that a sensor placed observing venous blood at that place would be calibrated to zero hydrostatic (blood static) pressure at that point. At such a point, the arterial blood can be separately measured owing to its different spectral characteristics, which are well known in the art. For a sufficiently high sampling resolution of the measuring system, cyclical properties of the blood circulation can be observed.

Thus, calibrating for a mean zero, or zero and any other constant hydrostatic pressure in point 80, and at an additional point 82 in the leg at which the mean hydrostatic pressure of a column of blood can be easily calculated, provides for a calibration curve. The difference in blood pressure between the

point of zero pressure 80 and point 82 is a function of the weight of the column of blood between these two points, which is a function of difference in height, Δh, between the two points. Such a calibration curve would provide a function between the hydrostatic (blood static) pressure of blood at a specific measuring location, and the optical information collected by the sensor unit.

Alternatively, the differences in hydrostatic blood pressures may be measured between the any two points and is not restricted to measurement between zero pressure and a second point. The difference in hydrostatic blood pressure refers either to the difference in elevation of any two points or alternatively to the difference in one point due to changing the relative height of the point. For instance, in the latter case, the difference in hydrostatic blood pressure can be measured when a leg or arm is moved from one position to a different position.

Normalization of the curve can be achieved by establishing a waveform by way of processing the received signal, filtering out noise, and irrelevant variables such as movement of the patient. This is achieved, for example, by comparing the measured rhythm at two different measurement sites, in this way common features of the wave can be established, whereas transient noises or effects common to only one site can be avoided.

In Fig. 1, to which reference is again made, a wave is illustrated in two different points in the body, showing schematically the amount of blood momentarily present in the respective tissues. It can be seen that, although the magnitudes are different and the phases are shifted, the normal waveform is similar. Phase shifting occurs as a result of the time delay in one site relative to

another site which is closer to the heart. It will be appreciated that the heart is used for exemplar purposes only and any other organ, such as the liver, kidney, brain and eyes, may be used as a reference point. The attenuation of the wave is caused by dissipation of the driving energy in the body, it is also influenced by the viscosity of the blood. Thus, by using the common characteristics of the waves from two different measurements at different sites, a common waveform can be subsequently established.

Cardiac Output

Integration of the waveform gives the relative cardiac output. By normalizing the diameter of the blood conduit, the absolute value of the cardiac output is obtained.

Optical acuity, sampling resolution, and resolution of the system

In order to resolve properties of the circulatory system at the cellular or even sub-cellular level, a narrow beam of light is provided by the transmitter such that the resolution of measurement is appropriate. A typical red blood cell is 8 microns in diameter, which implies that a narrower beam is required for possibly assessing a single cell at a time. To achieve such a high resolution of measurement, a short duration of light and subsequent detection is required as well, so that, within a specific time frame, a specific cell can be measured. This can be achieved by using a laser diode having a narrow beam, typically about 5 - 100 microns at the site of measurement, and short bursts as described above. It will be appreciated that though it is preferable to assess red blood cells because of their dimension, it is also possible to assess white or other blood cells.

Statistical treatment of the measurements can be utilized in order to define circulatory system parameters. For example, a change of speed of blood cells may be brought about by a change in blood pressure, or blood viscosity, or it may depend on cardiac output characteristics.

It will be appreciated that the measurements may also be used in many applications. For example, the measurements can indicate the effect of drugs and stimulants. By comparing the vitality of tissue in different areas, the information can be used to define the border line between dead and live tissue, for example, which is useful for general surgery and plastic surgery. Additionally, the measurements may be used for bio-feedback.

The measurements are also useful for indicating the nature of the blood flow. For example, turbulent or laminar flow are useful parameters to indicate any restrictions in the arteries.

Differential depth measurement

A device according to the method of the invention is used to measure properties of tissues, including blood, in different depths. Such a device is shown in Fig. 6, to which reference is now made. A transmitter 12 sends pulses of light that penetrate a tissue 54 and interact with the tissue 54 resulting in attenuation of the pulse. The light beam 52, which comprises discrete pulses, is partially absorbed at the surface and partially penetrates tissue 54. Along beam 52, two different points 66 and 58 of reflection are shown. Some energy is diverted away from light path 52, at each of these points, and is detected by parallel detectors 16A and 16B corresponding to points 56 and 58, respectively. Embodiments

having different configurations of transmitters and detectors can be implemented for acquiring data about blood circulation at different depths.

Similarly, the diameter of the blood conduit can be determined in order to normalize the cardiac output.

Thus, the incremental path or time of a light beam in the tissue 54 coming from point 58 as compared to point 56 can be calculated. In parallel, the incremental attenuation of the light energy is also calculated by comparing the amount of energy coming from point 58 with the one coming from point 56. For a uniform tissue, the attenuation is uniform, constituting a linear function of travel time or length of path in the tissue. However, since the tissue under study is probably either non-uniform or suspected to contain non-uniform portions, the attenuation of a pulse cannot serve as an unequivocal measure of a depth of penetration on the one hand or typify the tissue optically on the other hand. In order to overcome the limitation of such a system, the chain of bursts such as is shown in Fig. 3 can be modulated by a superimposed sine wave.

To show the implementation of the invention, reference is now made to Fig. 7, which is a schematic illustration of bursts modulated by a superimposed energy wave.

Each pulse within a burst can be registered as to its relation to the superimposed cycle by comparing it to its neighboring pulses. Thus pulse 71 at the beginning of third burst C, is recognized by the long gap in time before the occurrence of a new pulse (in burst D) and burst D is the final burst in the half-cycle.

The phase difference of the cycle of pulses between the two points, as measured simultaneously in two different points, is dependent upon the distance between the same two points. Thus, the tissue is in such a case can be considered to be homogeneous, if the geometrical path of the beam within the tissue is the only factor to cause a phase difference. If however the expected phase difference does not show up, then a non-uniformity must exist in the tissue which causes the deviation of the phase difference from the one expected from purely geometrical consideration. The results may be output in any suitable form including 2-Dimensional graphs, 3-Dimensional format and by section slices.

It will be appreciated by persons skilled in the art that the present invention is not limited to the medical diagnostics of humans but is also applicable to livestock and animals, including chickens, cows, race horses, rabbits and monkeys, for example.

It will also be appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described herein above. Rather the scope of the invention is defined by the claims which follow:

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CLAIMS

1. A device for detecting and monitoring the properties of circulating blood elements in a body, the device comprising:

at least one transmitter for transmitting light through a tissue containing said blood elements with at least one spectral component of light;

at least one detector for detecting at least a portion of the light transmitted through said tissue;

a controller connected to said at least one detector and said transmitter, said controller controlling said transmitted light and determining the travel time of said transmitted light; and

a processing unit connected to said controller, wherein said processing unit processes medical and physiological information about said tissue.

2. A device according to claim 1 wherein said transmitter includes means for emitting at least one pulse of illumination, each of said at least one pulses of illumination having at least one spectral component of light.

3. A device according to claim 2 wherein said each of said at least one pulses have similar magnitude proportional to their corresponding energy level.

4. A device according to claim 2 wherein said each of said at least one pulses are equally spaced apart.

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5. A device according to claim 1 wherein said at least one detector comprises at least two detectors arranged in parallel.

6. A device according to claim 2 wherein said at least one pulses carry Direct Current (DC) energy.

7. A method for monitoring properties of the blood circulation system in a tissue, the method comprising the steps of:

transmitting light energy at said tissue,

detecting said light energy after having been affected by said tissue,

determining at least one property of said tissue.

8. A method according to claim 7 wherein said step of determining said at least one property comprises the steps of:

determining the attenuation of said light energy;

calculating the time for said light energy from transmission to detection; and

relating said attenuation and said travel time to said at least one property.

9. A method according to claim 7 wherein said light energy is in the form of bursts containing spaced pulses, each of said spaced pulses having at least one spectral band.

10. A method according to claim 7 wherein said step of determining comprises the step of calibrating the static blood pressure at least two pre-determined points.

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11. A method according to claim 10, wherein at least one of said pre-determined points has a hydrostatic blood pressure value of zero.

12. A method according to claim 10, wherein at least one of said pre-determined points has a hydrostatic blood pressure value of zero.

13. A method according to claim 7 wherein said step of determining comprises the step of normalization, said normalization comprising the steps of:

processing the received signal at at least one measurement point to obtain a waveform; and

determining the time lag of said waveform, thereby to determine the group delay and/or viscosity.

14. A method according to claim 7 wherein said at least one property comprises one of a group including circulatory system parameters at the cellular and sub-cellular level, systolic pressure, diastolic pressure, blood viscosity, change in viscosity, cardiac output and blood flow, saturation of oxygen and systolic waveform.

15. A method according to claim 7 wherein said step of determining comprises the step of measuring the blood circulation at different depths.

16. A method according to claim 7 wherein said step of detecting comprises the step of detecting light transmitted through or reflected by said tissue.

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17. A method according to claim 7 wherein said step of detecting comprises the step of detecting the change in frequency of reflected pulses received, thereby to determine the blood velocity.

18. A method according to claim 7 wherein said step of detecting comprises the flow character.

19. A method according to claim 7 and further comprising the step of displaying at least one of said properties in at least one of group of formats including two-dimensional and three-dimensional form.

20. A method according to claim 19 and further comprising the step of changing the physiological status of the body thereby to alter the input of medical and physiological information about said tissue to said processing unit.

21. A method according to claim 7 wherein said light is transmitted via one of a group of sources including semi-conductor light emitting diodes (LED) and diode lasers.

22. A system according to claim 1 wherein said light is transmitted via one of a group of sources including semi-conductor light emitting diodes (LED) and diode lasers.

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