(54) Title: AN IMPROVED METHOD AND APPARATUS FOR THE DETECTION OF MEDICAL CONDITIONS OF SHOCK AND PRE-SHOCK
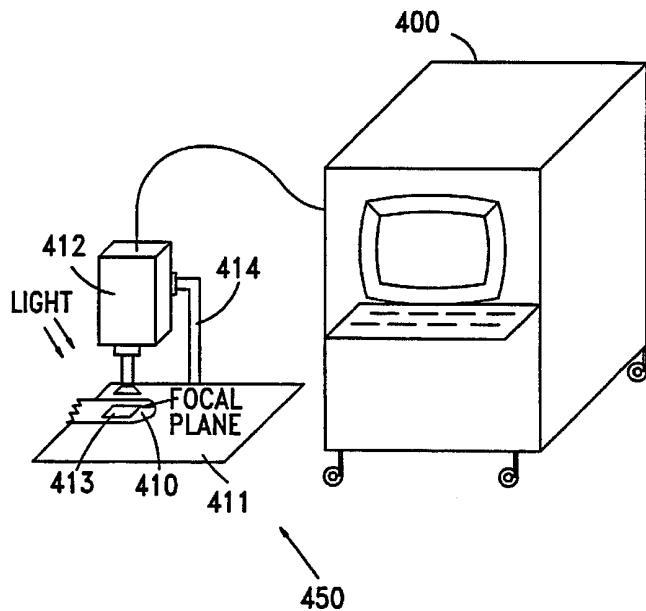
(57) Abstract: Method and apparatus for the diagnosis and/or early detection of physiological distress in a patient and of recovery of a patient from actual state of physiological distress by measuring the filling time of blood vessels subjacent to an area of the skin of the patient. An image of an area to be gauged for color is acquired, so as to obtain a base-line color measurement. The filling time of blood vessels in the area is determined by comparison of the color of one or more additional images of the gauged area with the base-line measurement.

AN IMPROVED METHOD AND APPARATUS FOR THE DETECTION OF MEDICAL CONDITIONS OF SHOCK AND PRE-SHOCK

Field of the Invention

The present invention relates to the field of medical diagnosis instrumentation. More particularly, the invention relates to a method and apparatus, for non-invasive detection and monitoring of physiological states, for the diagnosis of shock, pre-shock and cardio-pulmonary distress in a patient, and of recovery of a patient from shock pre-shock and cardio-pulmonary distress by monitoring changes in the capillary flow in skin areas of peripheral body organs.

Background of the Invention

The normal color of the skin in most locations of the human body is between pink and red. This color is mainly determined by the amount of blood flowing in the capillaries, through which blood flows from the arterioles to the venules. The present invention is based on a non-invasive detection of hemodynamic changes in (and particularly the reduction of) the skin arteriolar-capillary flow during the states of shock, pre-shock and cardio-pulmonary distress.

The physiological principle of the invention is shock: Shock is a clinical syndrome. The diagnosis of shock is based on clinical appreciation of the presence of inadequate blood flow (perfusion) to organs and tissues. In most cases of shock the condition is reversible, but if lasts to long, it can cause an irreversible damage to the tissues and in severe cases even death. One of the most common types of shock is hypovolemic shock, which is the

- 2 -

result of volume loss. For instance, massive blood loss (hemorrhage) or loss of body fluids due to severe dehydration, vomiting or diarrhea. An early compensatory mechanism in hypovolemic shock is increasing the resistance of the skin tissue arterioles in order to reduce blood perfusion to the skin tissue enabling an adequate perfusion to vital organs (brain, heart, and kidneys). The process of increasing arteriolar resistance is called vasoconstriction and is done by constricting the arteriolar walls and diminishing the vessel's diameter. This phenomenon of peripheral arteriolar vasoconstriction appears in some other types of shock (such as in shock as a result of heart failure). The vasoconstriction of the skin tissue arterioles and the reduction if the arteriolar blood flow leads to a reduction of the capillaries blood flow (poor perfusion to the skin). An important clinical sign of poor perfusion to the skin is the estimation of Capillary Filling Time (CFT). Upon applying minor pressure on a specific area of the skin, the capillaries under the depressed area collapse and blood is forced therefrom (blanched), causing the skin color under the depressed area to become white. Upon releasing the pressure abruptly, blood flows back into the capillaries and the original skin color returns. The CFT is defined as the estimated time for the original skin color to return after blanching. In the clinical practice, prolongation of the CFT of more than 2 seconds is indicating a state of poor skin perfusion (shock) or a cold ambient temperature. If the condition of shock continues, the arteriolar vasoconstriction increases even further and the prolongation of the CFT continues. On the other hand, appropriate treatment of shock decreases the vasoconstriction and shortens the CFT. Similar homodynamic changes occur in some other types of shock.

Another type of shock is associated with cardiovascular failures. Cardiovascular failure results from a substantial damage to the heart muscle (such as during an acute myocardial infarct), to a major blood

- 3 -

vessel (such as in rupture of the aorta), or to other component of the heart (e.g., valvular damage to the endocard).

According to this physiological principle of hemodynamic compensation in shock, an accurate measuring of the CFT is a direct non-invasive method to evaluate perfusion in the condition of shock. The other known non-invasive methods to evaluate shock are:

- Blood pressure: an indirect parameter of shock (do not evaluate perfusion). However, the measurement of blood pressure identifies shock only in late stages (de-compensated shock).

-Heart rate: an indirect parameter of shock (do not evaluate perfusion). The specificity of this measurement is low because heart rate is also increases in other common physiological conditions (e.g. anxiety, pain). Therefore, a method that enables an early identification of shock, and the monitoring of the severity of the shock and the patient immediate response to treatment (shortening of CFT is a proof of an improvement in peripheral perfusion) is desired.

early hypovolemic shock, myocardial ischemia and Cardio-pulmonary distress are all associated with some reduction of arteriolar-capillary flow in skin areas. Early hypovolemic shock is in fact an early stage of shock, in which the blood pressure of the patient is usually normal. It is therefore desired to detect such early stage in order to provide an appropriate medical treatment at this stage, so as to prevent deterioration to shock state. Since peripheral arteriolar vasoconstriction is an early manifestation of hypovolemic shock, the detection of CFT prolongation is a diagnosis of an early shock state.

Another state, in which inadequate blood supply is provided to the heart muscle is myocardial ischemia. Peripheral arteriolar vasoconstriction is a

- 4 -

known manifestation of myocardial ischemia. In many cases myocardial ischemia is the first stage in the evaluation of acute damage to the heart muscle and/or of cardiovascular failure. The clinical manifestations of this condition are various and sometimes misleading. It is therefore desired to detect such first stage in order to provide an appropriate medical treatment at this stage, so as to prevent deterioration to a irreversible damage to the heart muscle (i.e., to a myocardial infarct).

Cardiopulmonary distress refers to diseases or medical conditions that induce impairment in the cardiopulmonary function that causes peripheral arteriolar vasoconstriction, for example, congestive heart failure, chronic lung disease, drug effect or side effect, or drug toxicity.

Other physiological distress which is associated with the reduction of arteriolar-capillary flow in skin areas is dehydration, which may be severe as a result of vomiting, diarrhea, severe burns or extreme environmental conditions. Such physiological conditions involve increased blood viscosity resulting from significant loss of fluids, which reduces the arteriolar-capillary flow. In addition, medical or surgical conditions, which comprise a reduction in blood flow to a limb (e.g., peripheral vascular disease, reconstruction of skin flaps, etc.) is also associated with the reduction of arteriolar-capillary flow in skin areas and prolongation of the CFT.

The diagnosis in most of the aforementioned conditions is difficult because the clinical signs are minimal, or even absent. The biological response in these conditions is the constriction of the arteriolar walls, which results in the reduction of the skin capillary flow and prolongation of the CFT. This CFT prolongation is detected and monitored.

- 5 -

US Patent 3,698,382 discloses an apparatus for measuring the veno-CFT, which employs intermittent and uniform pressure to the skin of a patient. The apparatus comprises a light source for illuminating a skin area and photoelectric monitoring means that is sensitive to the coloration of the skin area. The apparatus measures the rate of return of color to the skin area from pressure release. However, this apparatus suffers from interference of external light and requires an opaque housing for the monitoring means. In addition, the mechanical arrangement required for maintaining uniform pressure, required for better accuracy is cumbersome. In addition, US Patent 3,698,382 does not detect any continuos changes of the CFT (i.e., does not provide $\Delta CFT/\Delta t$- curve)

All the methods described above have not yet provided satisfactory solutions to the problem of providing an apparatus for the diagnosis of shock, pre-shock and cardio-pulmonary distress in a patient and of recovery of a patient from actual state of shock, which is accurate and simple to use.

It is an object of the present invention to provide a non-invasive apparatus for the diagnosis of pre-shock and cardio-pulmonary distress pre-shock state in a patient and of recovery of a patient from actual state of shock, pre-shock and cardio-pulmonary distress, which overcomes the drawbacks of prior art.

It is a further object of the present invention to provide a non-invasive apparatus for the diagnosis of pre-shock and cardio-pulmonary distress pre-shock state in a patient and of recovery of a patient from actual state of shock, that does not require a uniform pressure on the skin.

It is still another object of the present invention to provide a non-invasive apparatus for the diagnosis of pre-shock and cardio-pulmonary distress pre-shock state in a patient and of recovery of a patient from actual state of shock, that provides an indication to the user whenever the magnitude and/or the duration of the pressure applied on the skin area is not sufficient.

It is still another object of the present invention to provide a non-invasive apparatus for the diagnosis and early detection of cardio-pulmonary distress in a patient.

It is still another object of the present invention to provide a non-invasive apparatus for the diagnosis and early detection of cardiovascular failure in a patient.

It is still another object of the present invention to provide a non-invasive apparatus for the diagnosis and early detection of myocardial ischemia in a patient.

It is still another object of the present invention to provide a non-invasive apparatus for the diagnosis and early detection of dehydration state in a patient.

It is yet a further object of the present invention to provide a non-invasive apparatus for a sensitive identification of clinical deterioration or improvement of the patient and the effectiveness of the treatment.

Other objects and advantages of the invention will become apparent as the description proceeds.

Summary of the Invention

The present invention is directed to a method for the diagnosis and/or early detection of physiological distress in a patient and of recovery of a patient from physiological distress by measuring the filling time of blood vessels subjacent to an area of the skin of the patient. Image acquisition means are positioned, so that an area of the patient's skin is essentially within its focal plane of the image acquisition means. The area, having an original color, is illuminated with background light or with a light source, at a radiation level which is sufficient for enabling the image acquisition means to discriminate between colors. An image of the area is acquired by the image acquisition means, and an electrical signal, which represents of the color of the area, is produced. The value of the electrical signal which corresponding to the original color is stored in a memory. Pressure is applied on the area, of a strength and duration sufficient for forcing blood to flow out from the blood vessels, and for obtaining a signal having a value which corresponds to the maximum whitening of the area. The filling time is measured by rapidly releasing the pressure and subsequently measuring and displaying the total period of time from maximum whitening until the value of the electrical signal is essentially the same as the stored value. The physiological distress is determined from the total period of time. By using the term "physiological distress" it is meant to include any state selected from the group:

- actual shock state;
- pre-shock state;
- hypovolemic shock;
- cardiovascular failure;
- cardio-pulmonary distress;
- myocardial ischemia;
- dehydration;
- peripheral vascular disease; and

- 8 -

-      post surgical skin states.

Pressure is applied toward the surface of the patient's limb, by attaching a rigid transducer containing a light source and a light sensor and having a transparent wall being in contact with the limb, and applying a controlled force on said rigid transducer. The applied pressure can automated and/or controlled by adding a linear motor to the transducer for applying force on said transducer. Alternatively, an electromagnet, or a rotational motor having an excentric movement mechanism, can be added to the transducer for applying force on said transducer. The transducer may be controlled and/or may provide measured data by using wireless transmission.

Preferably, the amplitude value of the second electrical signal is sampled at a predetermined rate during the measurement and said sampled values are stored. The filling time can be extrapolated by processing at least a portion of said stored values whenever the strength and/or the duration of the applied pressure is not sufficient for obtaining maximum whitening. An alert signal is provided whenever the strength and/or the duration of the applied pressure is not sufficient for obtaining maximum whitening. The pressure is applied and released manually or automatically.

Preferably, the measurement results are verified by displaying a graphical representation of the measured filling rate. The measurement of the filling time is repeated at different time intervals, the values of all measurements are stored, and a graphical representation of the measured filling times is displayed as a function of time, so as to obtain an indication related to the recovery of the patient from the physiological distress.

The invention is also directed to an apparatus for the diagnosis and/or early detection of physiological distress in a patient and of recovery of a

- 9 -

patient from physiological distress, according to changes in the color of the patient's skin in response to an applied pressure on the skin, the pressure causing blood to flow out from blood vessels being subjacent to the skin. The apparatus comprises image acquisition means, such as a video camera, for acquiring an image of an area of the skin of the patient, to be gauged for color, the image acquisition means being positioned, so that the area is essentially within the focal plane of the image acquisition means; circuitry for obtaining a base-line color measurement using the acquired image data when essentially no pressure is applied; and circuitry for comparing the color of the area with the base-line color measurement, thereby determining the filling time of blood vessels in the area after releasing the pressure. Preferably, the apparatus further comprises means for illuminating area of the skin to be gauged for color, with light radiation in a level being sufficient for enabling the image acquisition means to discriminate between colors.

Preferably, the apparatus comprises circuitry for producing an electrical signal representative of the color of the area; circuitry for storing the value of the electrical signal which corresponds to the original color of the area; a processor for processing data collected by the transducer and/or by the image acquisition means in combination with the stored data, for measuring the filling time after releasing the pressure; and a display for graphically displaying the processed data. The apparatus further comprises a transducer for applying pressure on the area, and for obtaining a signal value which corresponds to maximum whitening of the area; circuitry for sampling the image acquisition means for acquiring an image of an area of the skin of the patient, to be gauged for color; circuitry for sampling the value of the electrical signal at a predetermined rate during the measurement and for storing the sampled values; circuitry for providing an alert signal whenever the strength and/or the duration of the

- 10 -

applied pressure is not sufficient for obtaining maximum whitening; and a device for automatically applying and releasing pressure.

Preferably, the apparatus further comprises a rigid transducer containing the image acquisition means and having a transparent wall being in contact with a limb of the patient, for applying a controlled pressure on the surface of the limb.

Brief Description of the Drawings

The above and other characteristics and advantages of the invention will be better understood through the following illustrative and non-limitative detailed description of preferred embodiments thereof, with reference to the appended drawings, wherein:

- Fig. 1A schematically illustrates the structure of a skin color sensing apparatus for the diagnosis of pre-shock state in a patient by measuring the capillary filling time and rate, according to a preferred embodiment of the invention;

- Fig. 1B schematically illustrates the structure of a skin color sensing device for the diagnosis of pre-shock state in a patient by measuring the capillary filling time and rate, according to a preferred embodiment of the invention;

- Fig. 2 is a block diagram of an apparatus for the diagnosis of pre-shock state in a patient by measuring capillary filling time and rate, according to a preferred embodiment of the invention;

- Fig. 3A is a graphical representation of the measurement results of the CFT, according to a preferred embodiment of the invention;

- Fig. 3B is a graphical representation of the CFT as a function of the level of shock, for obtaining inferences related to the trend of the patient's physiological condition in reaction to medical treatment, according to a preferred embodiment of the invention; and

- 11 -

- Fig. 4 schematically illustrates the use an apparatus for the diagnosis of pre-shock state in a patient, according to a preferred embodiment of the invention.

Detailed Description of Preferred Embodiments

Fig. 1A schematically illustrates the structure of a skin color sensing apparatus for the diagnosis of pre-shock state in a patient by measuring the capillary filling time and rate, according to a preferred embodiment of the invention. The device 450 comprises a camera 412, such as a color video camera, which is fixed in place by an holder 414, above a rigid surface 411 (such as a table), to which the limb 410 of the patient is attached. The limb may be, for example, the patient's finger. The position of the camera is adjusted so that the skin area 413, which is photographed by the camera 412 for the purpose of the CFT measurement, is in, or close to, the focal plane of the lens. Pressure may applied on, and released from, the skin area 413 manually (e.g., by hand), or by using a mechanical apparatus, which may be automatically controlled.

Background light illuminates the skin area 413, and the light reflected from the surface of the skin area 413 is received in the lens of the camera 412. A minimal illumination level of 0.2 lux is sufficient, for most of the currently available modern cameras for color discrimination. The camera 412 produces an electrical signal having a magnitude, which corresponds to the color of the image, received by the camera. In the event that the illumination level of the background light is not sufficient, the skin area 413 can be illuminated with a light source, such as a conventional lamp or a Light Emitting Diode (LED).

A sensing device 100 is connected to a processing and display unit 400 with electrical cord, through which the CFT data is fed for processing and

- 12 -

display. The processing and display unit 400, which may be a personal computer that uses a control and processing software, processes the data received in the lens of the camera 412, and calculates the CFT total time and rate. Pressure is applied and released manually by the user, according to indications and/or instructions provided by the processing and display unit 400. The processing and display unit 400 may further comprise control circuitry for controlling automated application of pressure. The control circuitry may also be used to select a specific area for processing, taken from the imaged skin area. Such selection may be carried out, for example by software, which controls the processing. The sensing device may also be attached to other locations in the patient's body that are rich in subcutaneous blood vessels, such as to the lip or to the ear lobe, for measuring the CFT.

Fig. 1B schematically illustrates the structure of a skin color sensing device for the diagnosis of pre-shock state in a patient by measuring the capillary filling time and rate, according to a preferred embodiment of the invention. The device 100 comprises a camera 412, such as a color video camera, which is contained in a transparent external housing 102, so that most of the background light enters through the external housing and illuminates the skin surface 106.

The device 100 may further comprise an optional light source 101, such as a LED) that is operated by a power supply during measurement, when the background illumination level is not sufficient to enable the camera 412 to discriminate between colors. The external housing 102 may be light reflecting with an opening in its bottom side, so that most of the light radiation emitted from the light source 101 is directed toward the bottom side in one direction "A". The external housing 102 may also comprises an opaque internal housing 104, having an opening in its bottom side, so as to

- 13 -

enable light radiation to enter into the opaque internal housing space only from its bottom side. Using this structure, the camera 412 is assembled in the internal housing 104 for receiving most of the light reflected from the skin. The bottom sides of the external housing 102 and the internal housing 104 are aligned and covered with a transparent rigid layer 105, which is used to apply pressure on the skin while enabling light to pass through in both directions.

The transparent rigid layer 105 is brought in contact with the exterior layer 106 of the skin. Pressure is applied manually or automatically on the external housing 102 toward the skin surface in a perpendicular direction. The external housing delivers the pressure to the transparent rigid layer 105, which transfers it farther, through the exterior layer 106, to the interior layer 107 of the skin, that contains most of the subcutaneous blood vessels (capillaries). As a result, if the magnitude of the applied pressure is sufficient and maintained for sufficient period of time, blood is forced out of the capillaries that are under pressure, and the color of the interior layer 107 of skin becomes much brighter (i.e. close to white). The background light and/or the light radiation emitted from light source 101 penetrates into skin, and partially reflected back in direction "B", into the internal housing 104. The degree of reflection from the interior layer 107 is inversely related to the blood flow in the capillaries under pressure, since blood absorbs light. The reflected light enters the lens of the camera 412, which produces an electric signal, the magnitude of which is responsive to the instantaneous color of the skin. The position of the camera 412 within the device 100 is determined so that the exterior surface of the transparent rigid layer 105 is essentially in the focal plane of the camera 412. This positioning results in a clear and focused image that is received in the lens of the camera. A focused image improves the distinction between colors,

- 14 -

and therefore, improves the resolution and the accuracy of the measurement.

Under no pressure (i.e., full blood flow), the skin color is normally pink, and less light radiation is reflected back from the capillaries. Under pressure, (i.e., no blood flow), the skin color is normally white, and more light radiation is reflected back from the capillaries. Therefore, changes in the magnitude of the electric signal produced by the camera 412, provides an accurate measure of the capillary filling time and rate upon releasing the pressure from the skin. The device 100 is connected to a power supply for operating the optional light source 101 and to data collection, processing and display circuitry for processing the signals provided by the camera 412 and displaying the measurement results.

Fig. 2 is a block diagram of an apparatus for the diagnosis of pre-shock state in a patient by measuring capillary filling time and rate, according to a preferred embodiment of the invention. The apparatus 200 comprises the camera 412, and a frame grabber 206, for capturing the image received by the camera 412. The light reflected from the skin surface, is converted by the camera 412 to a corresponding video signal, such as a Composite Video or an Red-Green-Blue (RGB) Video signal (according to the type of camera that is used), that represents the received image. The video signal is fed into an electronic circuit (e.g., a Frame Grabber or a Video Capture circuit) which decodes the video signal and converts it into a corresponding array of digital values. The array is stored in a memory. Each memory cell, containing a digital value, represents the light intensity and the color of a portion of the received image. The camera 412 updates the image at a rate of 50 times per second, and therefore, the image information, generated by the frame grabber 206 and stored in the memory array, is also updated at the same rate. A rate of 50 times per second usually corresponds to video

- 15 -

cameras, which are compatible with Pulse Alteration by Line (PAL) video encoding standard. A rate of 60 times per second usually corresponds to video cameras, which are compatible with National Television System Committee (NTSC) video standard. Faster video cameras, which update the image in higher rate, can also be used.

The digital data is fed into a digital processor 207, which analyzes the data and display the results on a suitable display. The processor 207 samples a desired area of the image, which contains most of the tested skin area. At the next step, the processor 207 calculates the intensity of the essentially pink/red light, reflected by the tested skin area. The intensity of the reflected light is processed and normalized to a baseline, which may be the normal color of the patient's skin, when no pressure is applied. The image information is updated in a rate determined by the type of camera that is used. Therefore, the processor 207 continuously calculates the normalized intensity.

The display 208 comprises the display of the calculated results of the normalized intensity (i.e., the CFT), and of a graphical representation of the measurement process as a function of time. The graphical representation provides an indication whether the measurement results are reasonable or not, and if desired, the measurement can be repeated. According to a preferred embodiment of the invention, other data processed results, such as statistical data, can be also displayed to provide indications related to the reaction of the patient to medical treatment etc.

Fig. 3A is a graphical representation of the measurement results of the CFT, according to a preferred embodiment of the invention. At the first stage, no pressure is applied on the skin, and therefore the apparatus 200 can carry out calibration of the initial skin color of the patient. The value

- 16 -

of the calibration is stored for use at the end of the measurement. The calibration process is essential, since the normal color of the skin is individual and different from patient to patient. At the second stage, pressure is applied at a magnitude and duration that are sufficient to obtain maximum whitening of the skin color in the depressed area. The processor can be programmed to provide a warning signal (such as a beep) to the user, that the pressure is not sufficient or shorter than required. Obtaining maximum whitening of all the depressed area can be an indication to sufficient pressure. Longer and/or stronger pressure does not affect the skin color beyond maximum whitening. After obtaining maximum whitening, a corresponding signal is provided to the user to quickly release the pressure. The measurement of the CFT is started at that moment, t_0. The skin coloring changes from maximum whitening and begins to return to essentially the original color. Normally, the rate of filling is higher at the beginning of the filling process, and is lower as time lapses. The apparatus uses the stored calibration value to determine the moment t_f, at which the skin color recovered and the measurement is stopped. The recovery time can be defined according to the desired measurement accuracy. For example, t_f can be defined as the moment at which the value of the digital word that corresponds to the current skin color reaches a value being 90% of the value of the digital word that corresponds to the original skin color of that specific patient. In the graph of Fig. 3A, the CFT is given by $t_f - t_0$.

According to a preferred embodiment of the invention, the accuracy of the measurement can also be determined by the rate of change in the skin coloring, in the time interval that is close to the end of the measurement. The last segment of the graph is represented between the time points t_1 and t_f. The rate of change in this time interval is almost constant, and is almost not sensitive to the magnitude and duration of the applied

pressure. Therefore, the CFT can be extrapolated with relative accuracy from the time interval $t_f - t_i$. The CFT under normal conditions should be below 1 Sec. A CFT value above 2 Sec can be suspected as a pre-shock state. Longer CFT is considered to indicate more severe shock state.

Fig. 3B is a graphical representation of the CFT as a function of the shock-state, for obtaining inferences related to the trend of the patient's physiological condition in reaction to medical treatment, according to a preferred embodiment of the invention. At the first time interval, between time-points t_2 and t_3, the CFT value is below 2 seconds, and therefore, the patient is in normal condition (no shock). Early (mild) shock condition starts at time-points t_3, where the CFT value exceeds 2 seconds. As time lapses with no proper treatment, the shock becomes more severe, until the time-points t_4, which indicates the entry of the patient into a moderate shock condition(CFT value higher than 3 seconds). The next stage is indicated by the time-points t_5, which indicates the entry of the patient into a late (severe) shock condition (CFT value higher than 4 seconds). From point t_5 and forth, the CFT grows rapidly.

According to a preferred embodiment of the invention, a medical treatment is given to the patient, and the CFT is measured from that moment on a periodic basis. This measurement is used to determine whether the pre-shock or the actual shock condition is reversible. If the patient's reaction to the given treatment is positive, as time lapses, the CFT is reduced, indicating a constant improvement in the physiological condition of the patient, until the CFT value is reduced below the 2 Sec margin.

Fig. 4 schematically illustrates the use an apparatus for the diagnosis of pre-shock state in a patient, according to a preferred embodiment of the invention. The apparatus 200 comprises a skin color sensing device 100

- 18 -

attached by straps or by adhesive materials to a skin area which is rich in subcutaneous blood vessels, such as hand fingers, and a processing and display unit 400. The sensing device 100 is connected to the processing and display unit 400 with electrical cord, through which the CFT data is fed for processing and display. Pressure is applied and released manually by the user, according to indications and/or instructions provided by the processing and display unit 400. The sensing device may also be attached to other locations in the patient's body that are rich in subcutaneous blood vessels, such as to the lip or to the ear lobe, for measuring the CFT.

According to a preferred embodiment of the invention, an automatic measurement can be carried out by integrating a controllable mechanical apparatus into the sensing device 100 and to control the applied pressure and the release of pressure by an external controller. Such mechanical apparatus may comprise a miniature linear motor that produces linear movement rather than rotational movement. Alternatively, linear movement pressure can be applied by an electromagnet, or by a rotational motor with an excentric movement mechanism. The linear movement can be controlled to depress a movable member, such as a movable transparent rigid layer, against the skin and to release the pressure by a corresponding control command.

According to a preferred embodiment of the invention, the sensing device 100 and the processing and display unit 400 may further comprise receiving and transmitting circuits to enable wireless exchange of data and control commands, required for CFT measurements. Wireless connection enables a single processing and display unit 400 to control and monitor several sensing devices 100, each of which is attached to a different patient. Each sensing devices 100 is identified by a unique code assigned to it, to eliminate wrong association between processed data and a patient.

- 19 -

The above examples and description have of course been provided only for the purpose of illustrations, and are not intended to limit the invention in any way. As will be appreciated by the skilled person, the invention can be carried out in a great variety of ways, employing more than one technique from those described above, such as using pneumatic apparatus for applying pressure on the patient skin, or using an Infra-Red camera rather than a video camera, storing and displaying the history of CFT measurements of a patient, displaying the variation of the CFT curve with time, all without exceeding the scope of the invention.

- 20 -

CLAIMS

1. A method for the diagnosis and/or early detection of physiological distress in a patient and of recovery of a patient from actual state of physiological distress by measuring the filling time of blood vessels subjacent to an area of the skin of said patient, comprising acquiring an image of an area to be gauged for color, acquiring said image to obtain a base-line color measurement, and determining the filling time of blood vessels in said area by comparison of the color of one or more additional images of the gauged area with said base-line measurement.

2. A method according to claim 1, comprising:

   a) providing image acquisition means;

   b) positioning said image acquisition means, so that an area of the skin is essentially within the focal plane of said image acquisition means;

   c) causing said area, having an original color, to be illuminated with light radiation at a level sufficient for enabling said image acquisition means to discriminate between colors;

   d) acquiring an image of said area with said image acquisition means;

   e) producing an electrical signal representative of the color of said area;

   f) storing the value of said electrical signal which corresponding to said original color;

   g) applying pressure on said area of a strength and duration sufficient for forcing blood to flow out from said blood vessels, and for obtaining a signal having a value which corresponds to the maximum whitening of said area

   h) measuring the filling time by rapidly releasing said pressure and subsequently measuring and displaying the total period of time from maximum whitening until the value of said electrical signal is essentially the same as said stored value; ; and

i) determining the physiological distress from said total period of time.

3. A method according to claim 2, wherein the illumination is obtained from background light.

4. A method according to claim 2, wherein the illumination is obtained from a light source.

5. A method according to claim 2, further comprising:

   a) sampling the value of the electrical signal at a predetermined rate during the measurement and storing said sampled values; and

   b) extrapolating the filling time by processing at least a portion of said stored values whenever the strength and/or the duration of the applied pressure is not sufficient for obtaining maximum whitening.

6. A method according to claim 2, wherein an alert signal is provided whenever the strength and/or the duration of the applied pressure is not sufficient to obtain maximum whitening.

7. A method according to claim 2, wherein the pressure is applied and released automatically.

8. A method according to claim 2, further comprising verification of the measurement by displaying a graphical representation of the measured filling rate.

9. A method according to claim 2, further comprising:

   a) repeating the measurement of the filling time at different time intervals;

   b) storing the values of all measurements; and

- 22 -

c) displaying a graphical representation of the measured filling times as a function of time, thereby obtaining an indication related to deterioration in the patient's physiological condition, or to the recovery of the patient from physiological distress.

10.   A method according to claim 2, wherein the blood vessels are capillaries.

11.   A method according to claim 2, wherein the image acquisition means is a video camera.

12.   A method according to claim 2, wherein pressure is applied by attaching a rigid transducer containing the image acquisition means and having a transparent wall in contact with a limb of the patient, and applying a controlled force on said rigid transducer toward the surface of said limb.

13.   A method according to claim 12, wherein the applied pressure is automated and/or controlled by adding a linear motor to the transducer for applying force on said transducer.

14.   A method according to claim 12, wherein the applied pressure is automated and/or controlled by adding an electromagnet to the transducer for applying force on said transducer.

15.   A method according to claim 12, wherein the applied pressure is automated and/or controlled by adding a rotational motor having an excentric movement mechanism to the transducer for applying force on said transducer.

16.   A method according to claim 12, wherein the transducer is controlled and/or provides measured data by wireless transmission.

17.   A method according to claim 12, wherein the limb is a finger.

18.   A method according to claim 12, wherein the limb is a lip.

19.   A method according to claim 12, wherein the limb is an ear lobe.

20.   A method according to any one of claims 1, 2 and 9, wherein the physiological distress is selected from the group:
-     actual shock state;
-     pre-shock state;
-     hypovolemic shock;
-     cardiovascular failure;
-     cardio-pulmonary distress;
-     myocardial ischemia;
-     dehydration;
-     peripheral vascular disease; and
-     post surgical skin states.

21.   Apparatus for the diagnosis of physiological distress in a patient and of recovery of a patient from physiological distress, according to changes in the color of the patient's skin in response to an applied pressure on said skin, said pressure causing blood to flow out from blood vessels being subjacent to said skin, comprising:
   a) image acquisition means for acquiring an image of an area of the skin of said patient, to be gauged for color, said image acquisition means being positioned, so that said area is essentially within the focal plane of said image acquisition means;

- 24 -

b) circuitry for obtaining a base-line color measurement using the acquired image data when essentially no pressure is applied; and

c) circuitry for comparing the color of said area with the base-line color measurement, thereby determining the filling time of blood vessels in said area after releasing said pressure.

22. Apparatus according to claim 21, further comprising means for illuminating area of the skin to be gauged for color, with light radiation in a level being sufficient for enabling the image acquisition means to discriminate between colors;

23. Apparatus according to claim 21, comprising:

a) image acquisition means for acquiring an image of an area of the skin of said patient, to be gauged for color, said image acquisition means being positioned, so that said area is essentially within the focal plane of said image acquisition means;

b) circuitry for producing an electrical signal representative of the color of said area;

c) circuitry for storing the value of the electrical signal which corresponds to the original color of said area;

d) a processor for processing data collected by said transducer and/or by said image acquisition means in combination with the stored data, for measuring the filling time after releasing said pressure; and

e) a display for graphically displaying said processed data.

24. Apparatus according to claim 21 or 23, wherein the image acquisition means is a video camera.

25.   Apparatus according to claim 23, further comprising a transducer for applying pressure on said area, and for obtaining a signal value which corresponds to maximum whitening of said area;

26.   Apparatus according to claim 23, further comprising circuitry for sampling the image acquisition means for acquiring an image of an area of the skin of said patient, to be gauged for color, said image acquisition means being positioned, so that said area is essentially within the focal plane of said image acquisition means; value of the electrical signal at a predetermined rate during the measurement and for storing said sampled values.

27.   Apparatus according to claim 23, further comprising circuitry for providing an alert signal whenever the strength and/or the duration of the applied pressure is not sufficient for obtaining maximum whitening.

28.   Apparatus according to claim 23, further comprising apparatus for automatically applying and releasing pressure.

29.   Apparatus according to claim 23, further comprising a rigid transducer containing the image acquisition means and having a transparent wall being in contact with a limb of the patient, for applying a controlled pressure on the surface of said limb.

30.   Apparatus according to claim 29, further comprising a linear motor integrated into the transducer, for applying automated and/or controlled force on said transducer.

- 26 -

31.   Apparatus according to claim 29, further comprising an electromagnet integrated into the transducer, for applying automated and/or controlled force on said transducer.

32.   Apparatus according to claim 29, further comprising a rotational motor having an excentric movement mechanism to the transducer, for applying force on said transducer.

33.   Apparatus according to claim 29, in which the transducer and/or the image acquisition means comprises circuitry for wireless data transmission and/or control data.

34.   Apparatus according to claim 29, wherein the transducer is attached to the finger of the patient.

35.   Apparatus according to claim 29, wherein the transducer is attached to the lip of the patient.

36.   Apparatus according to claim 29, wherein the transducer is attached to the ear lobe of the patient.

37.   Apparatus according to claim 29, wherein the physiological distress is selected from the group:
-       actual shock state;
-       pre-shock state;
-       hypovolemic shock;
-       cardiovascular failure;
-       cardio-pulmonary distress;
-       myocardial ischemia;
-       dehydration;

- peripheral vascular disease; and

- post surgical skin states.

38. A method for the diagnosis and/or early detection of physiological distress in a patient and of recovery of a patient from physiological distress, substantially as described and illustrated.

39. Apparatus for the diagnosis and/or early detection of physiological distress in a patient and of recovery of a patient from physiological distress, substantially as described and illustrated.

400

412

LIGHT

414

FOCAL
PLANE

413   410   411

450

Fig. 1A

2/4
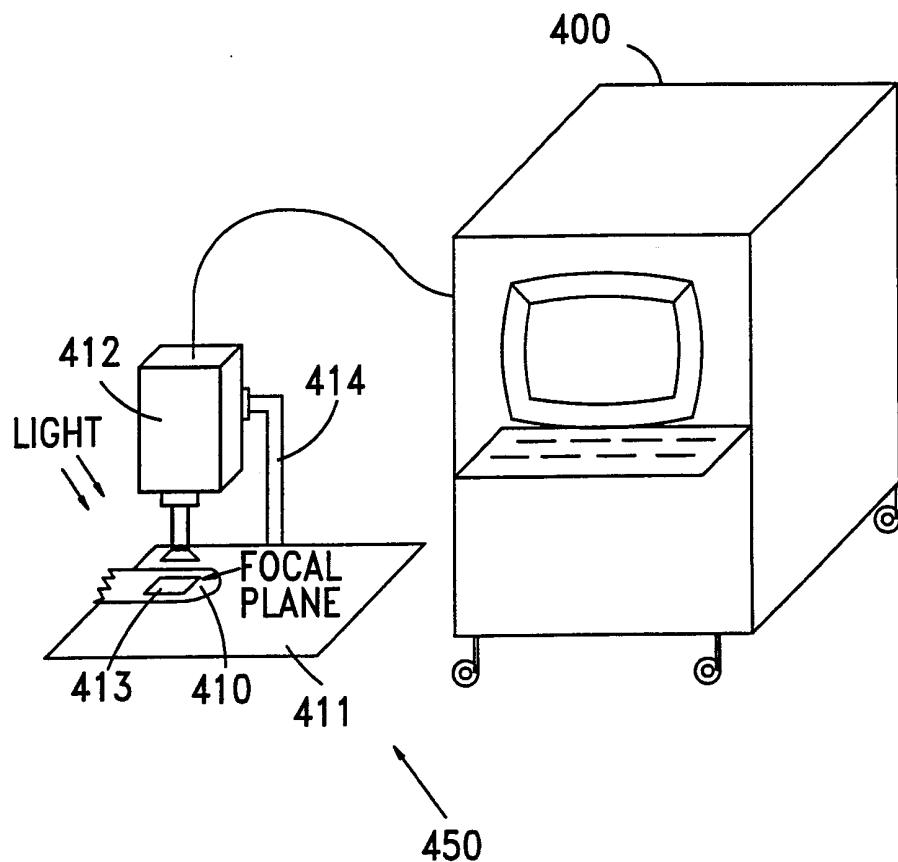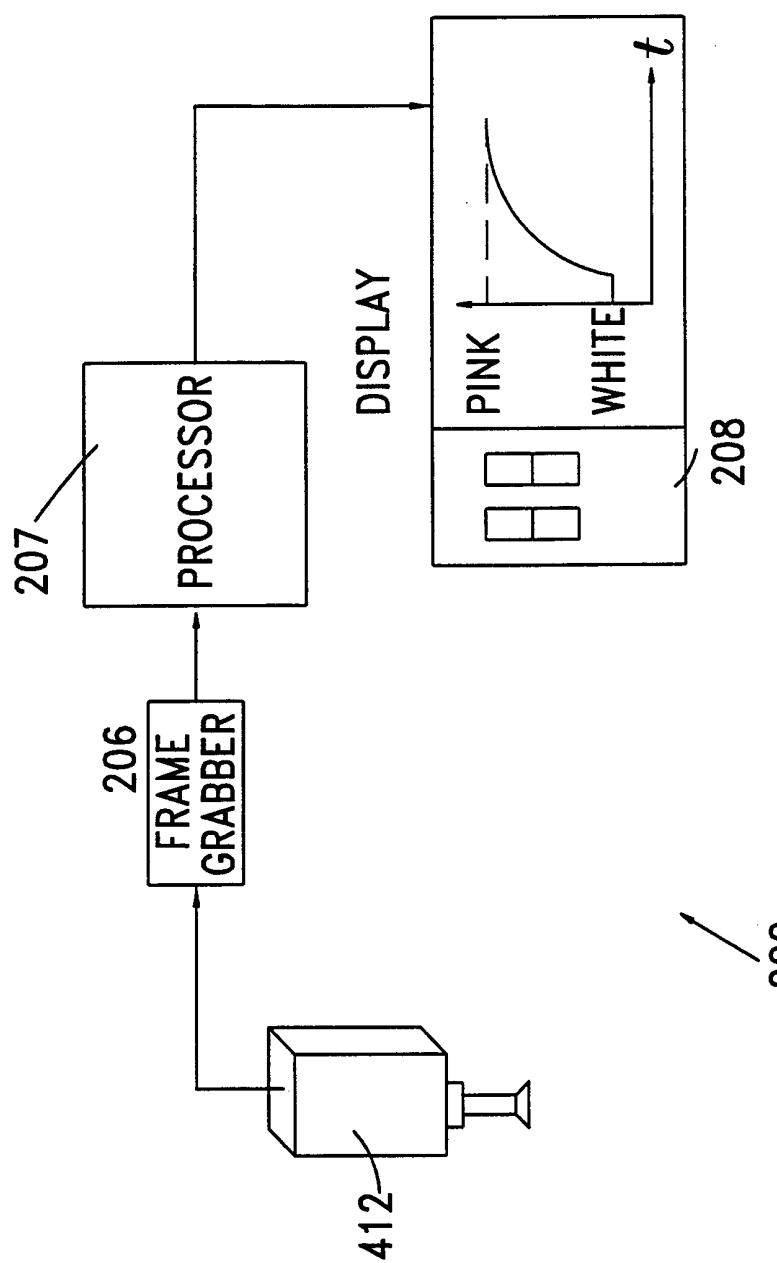
Fig. 2
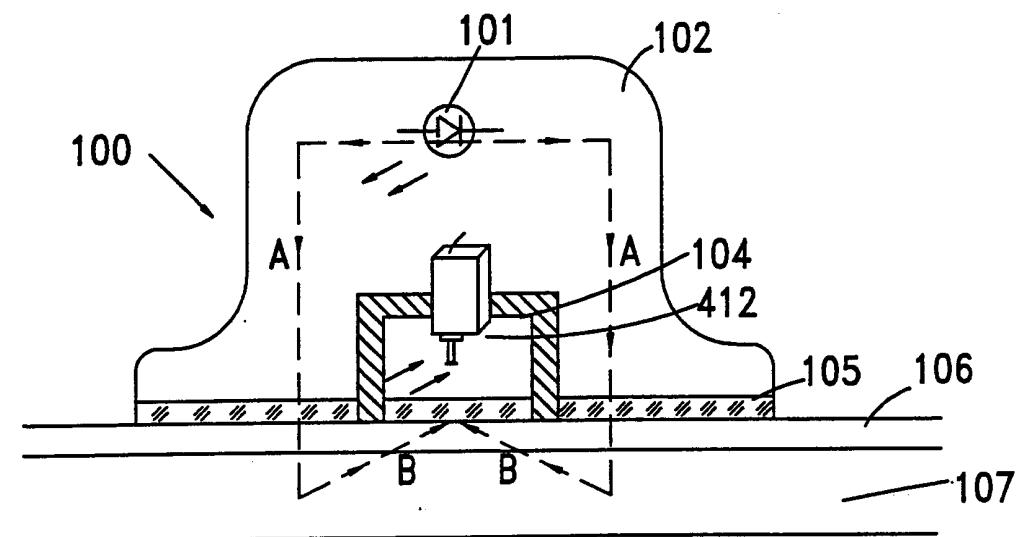
Fig. 1B
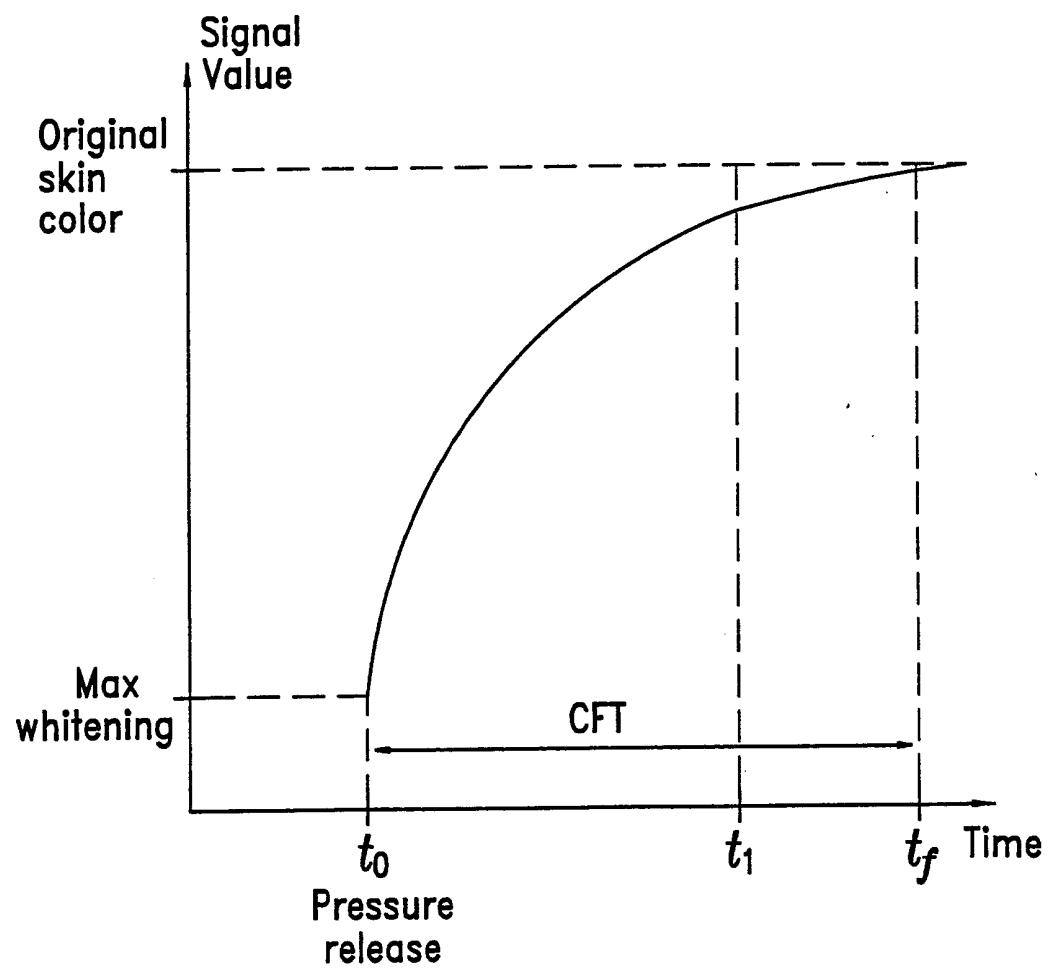
Fig. 3A
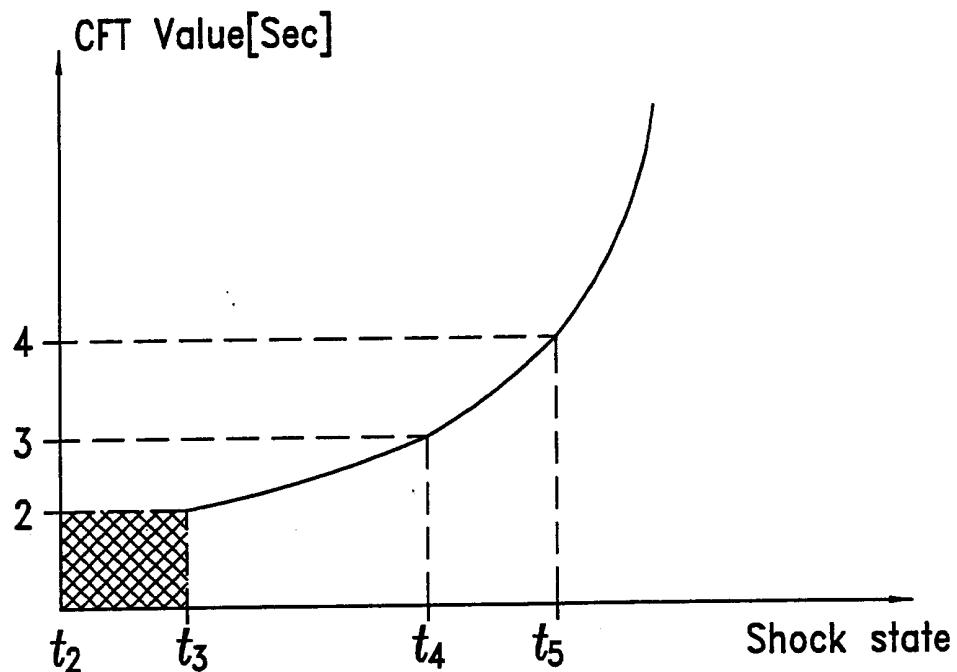
Fig. 3B
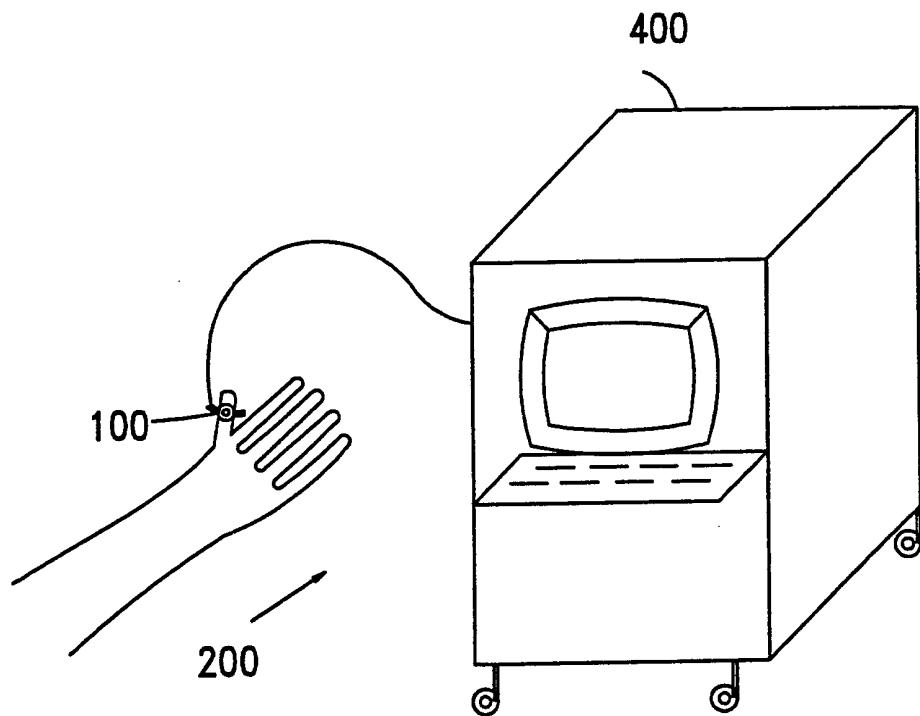
Fig. 4

INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7   A61B5/103

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)

IPC 7   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 data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category°	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 494 550 A (BLAZER & AL) 22 January 1985 (1985-01-22) column 5, line 45 -column 6, line 18 ---	1,2,4,8, 10, 20-23, 37-39
A	US 3 698 382 A (HOWELL) 17 October 1972 (1972-10-17) cited in the application the whole document -----	1,2,4, 7-10,12, 15, 20-23, 25,26, 28,29, 32,37-39

☐ Further documents are listed in the continuation of box C.   ☒ Patent family members are listed in annex.

Date of the actual completion of the international search	Date of mailing of the international search report
10 November 2000	17/11/2000

| 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

Lemercier, D |

Form PCT/ISA/210 (second sheet) (July 1992)

1

INTERNATIONAL SEARCH REPORT

...ormation on patent family members

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 4494550	A	22-01-1985	DE	3100610 A	29-07-1982
			AT	15320 T	15-09-1985
			DE	3172170 D	10-10-1985
			EP	0063649 A	03-11-1982
			JP	58036529 A	03-03-1983
US 3698382	A	17-10-1972	NONE		