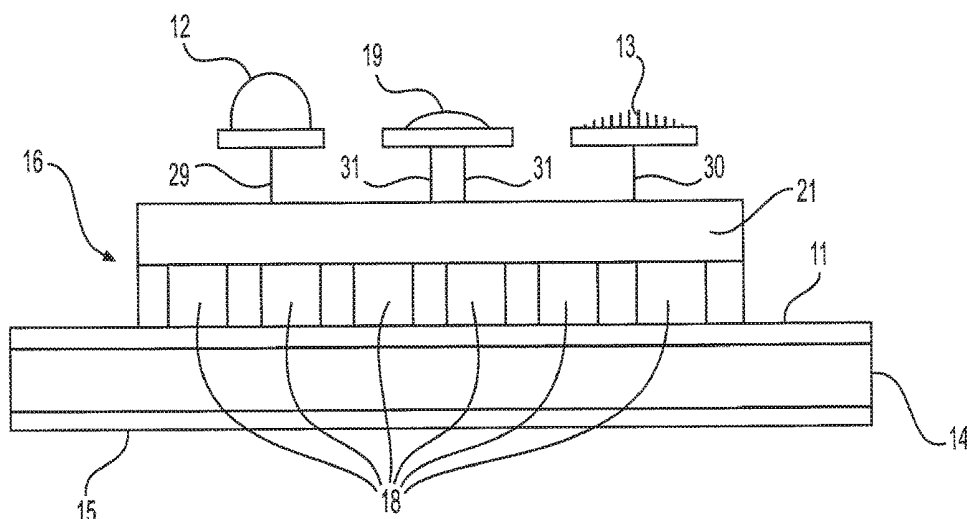




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Rodriquez(54) **STAND-ALONE CONTINUOUS CARDIAC
DOPPLER PULSE MONITORING PATCH
WITH INTEGRAL VISUAL AND AUDITORY
ALERTS, AND PATCH-DISPLAY SYSTEM
AND METHOD***5/02* (2013.01); *A61B 5/683* (2013.01); *A61B*
8/0866 (2013.01); *A61H 2201/5058* (2013.01);
A61H 31/004 (2013.01)(71) Applicant: **Gerardo Rodriquez, APO, AE (US)**(72) Inventor: **Gerardo Rodriquez, APO, AE (US)**(21) Appl. No.: **15/834,044**(22) Filed: **Dec. 6, 2017****Related U.S. Application Data**(60) Provisional application No. 62/430,822, filed on Dec.
6, 2016, provisional application No. 62/523,765, filed
on Jun. 22, 2017.**Publication Classification**(51) **Int. Cl.***A61B 8/00* (2006.01)*A61B 8/08* (2006.01)*A61B 8/02* (2006.01)*A61H 31/00* (2006.01)*A61B 5/02* (2006.01)*A61B 5/00* (2006.01)(52) **U.S. Cl.**CPC *A61B 8/4281* (2013.01); *A61B 8/488*
(2013.01); *A61B 8/02* (2013.01); *A61B 8/56*
(2013.01); *A61H 2230/25* (2013.01); *A61B*(57) **ABSTRACT**

A stand-alone continuous cardiac Doppler pulse monitoring patch provides visual and auditory signals that a pulse is detected or not detected in a human subject. The invention is a small patch with a peel-away adhesive surface that is applied to the skin of the subject, preferably near a large artery. The adhesive surface of the patch includes a conductive medium to enhance transmission and reception of ultrasonic waves. The patch includes an integral power source, transmitters and receivers to send and detect reflected ultrasonic waves, a transducer to convert the reflected waves into an electrical signal, a processor to analyze the signal, a light to indicate the presence and strength of a pulse, and a speaker also to indicate the presence and strength of a pulse. The Doppler effect of waves reflecting from blood pumped from a heart is used to detect a pulse in the subject. The presence of a pulse is analyzed by the processor to determine the frequency and strength of blood flow. The processor causes the light to blink at a rate to indicate the frequency of rhythmic blood flow. In a further embodiment, the processor analyzes the strength of the blood flow and causes the light to increase or decrease in intensity to reflect the strength or weakness of the flow. The processor may also drive a speaker to emit sounds, such as beeps, that indicate the frequency and strength of blood flow. The absence of blood flow may be indicated by the absence of light or sound, or by separate light or auditory signals.



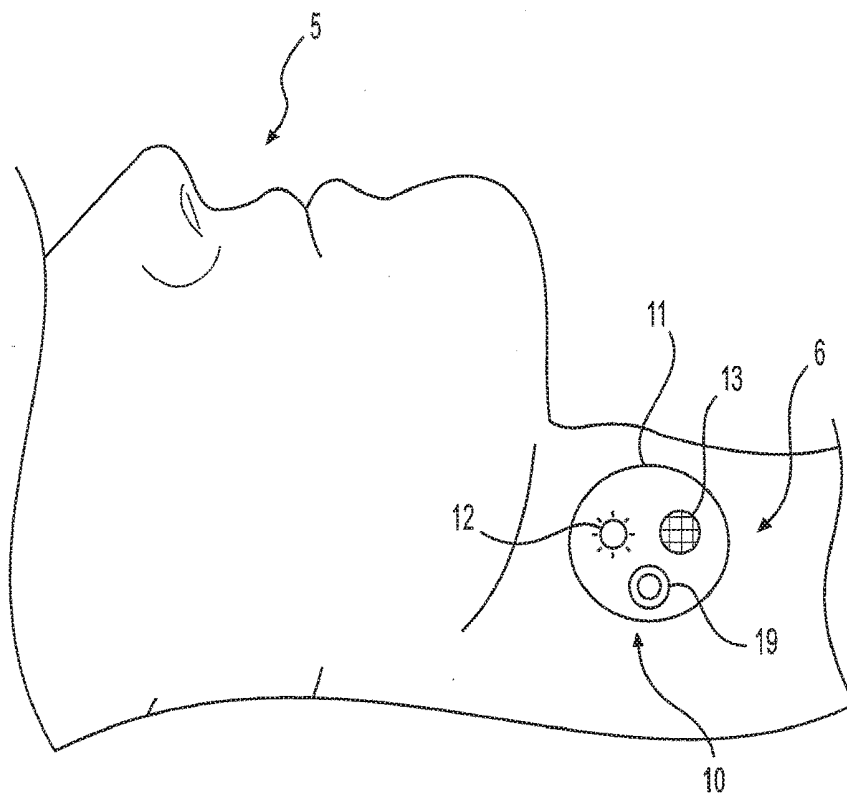


FIG. 1

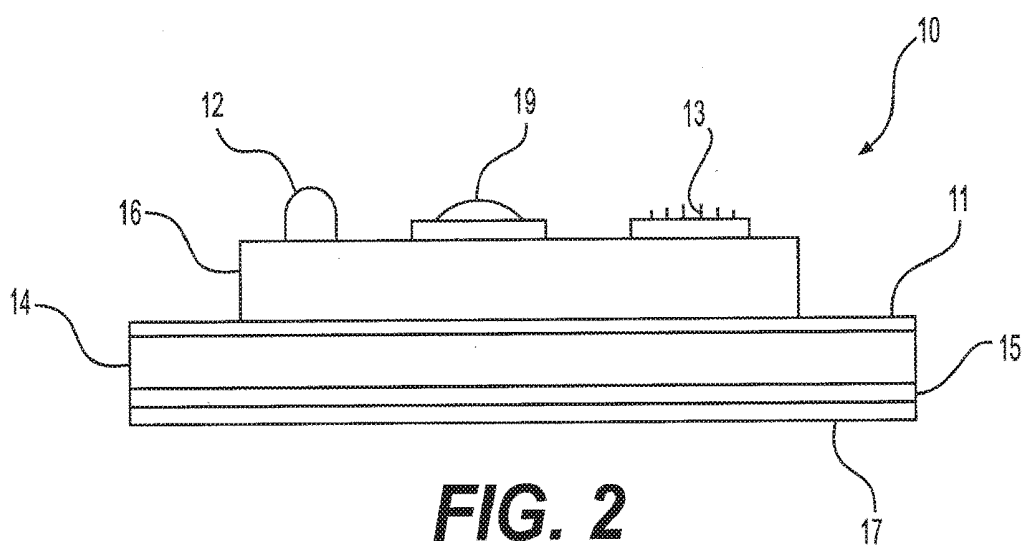


FIG. 2

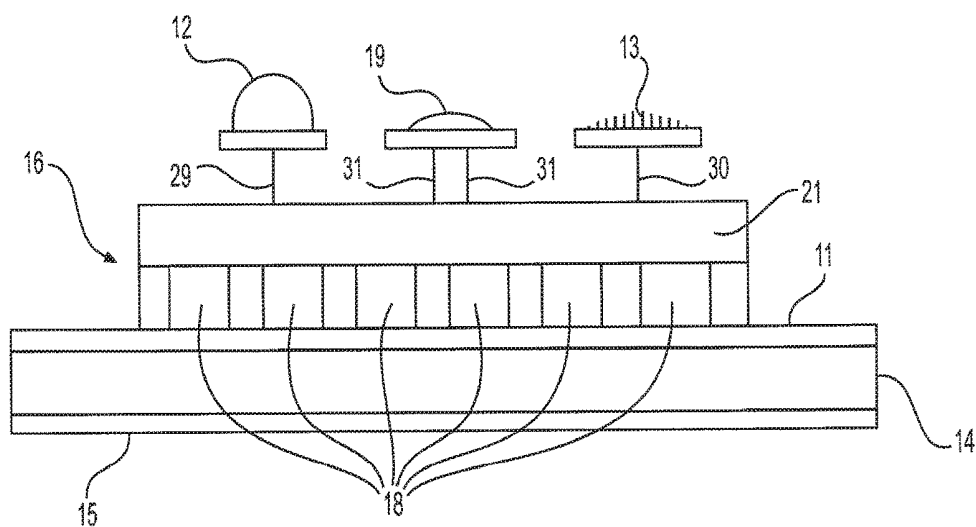


FIG. 3

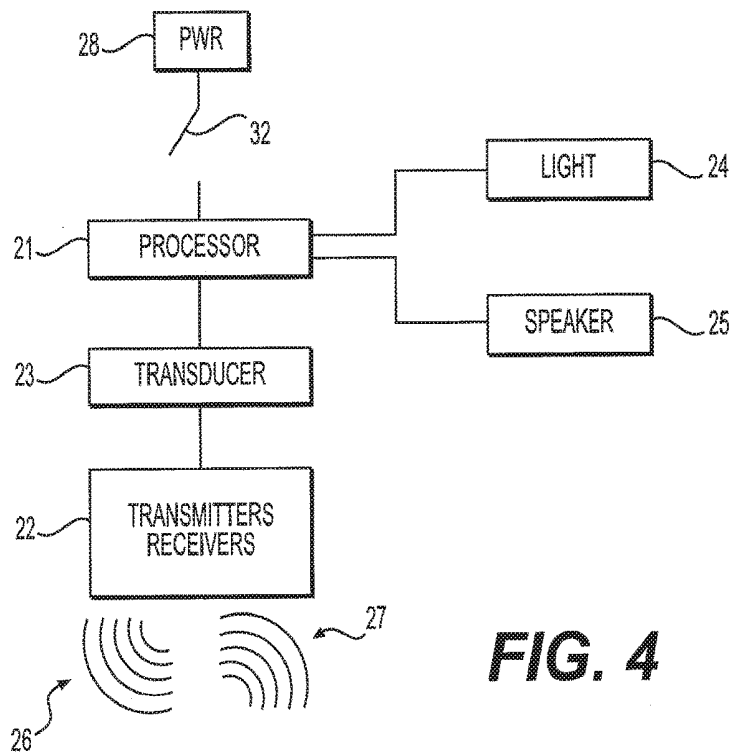


FIG. 4

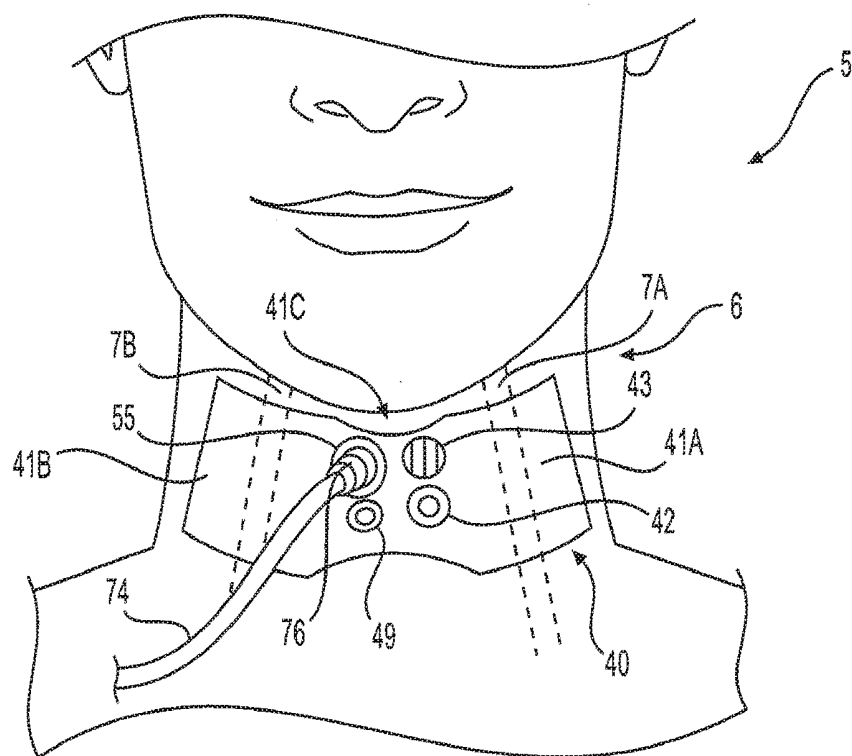


FIG. 5

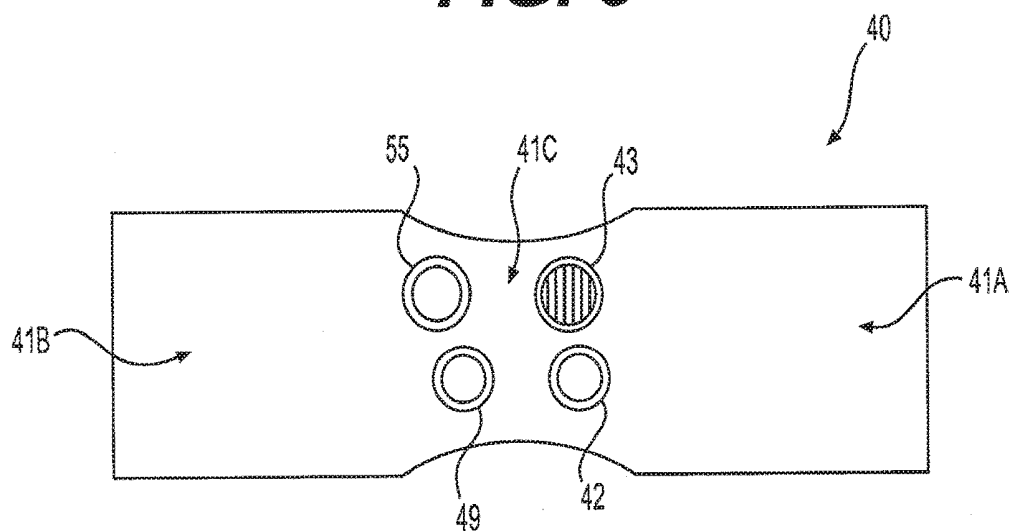


FIG. 6

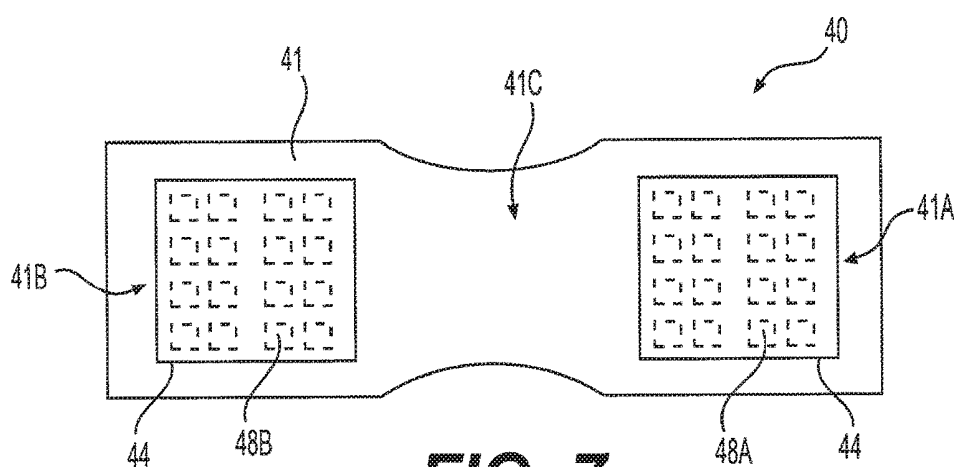


FIG. 7

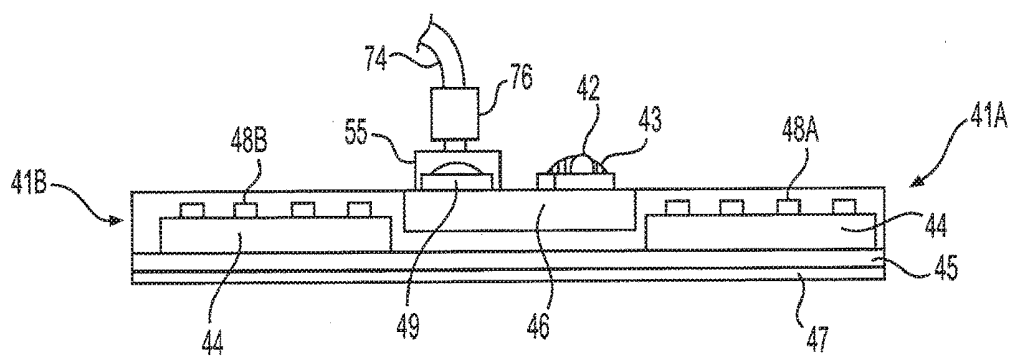


FIG. 8

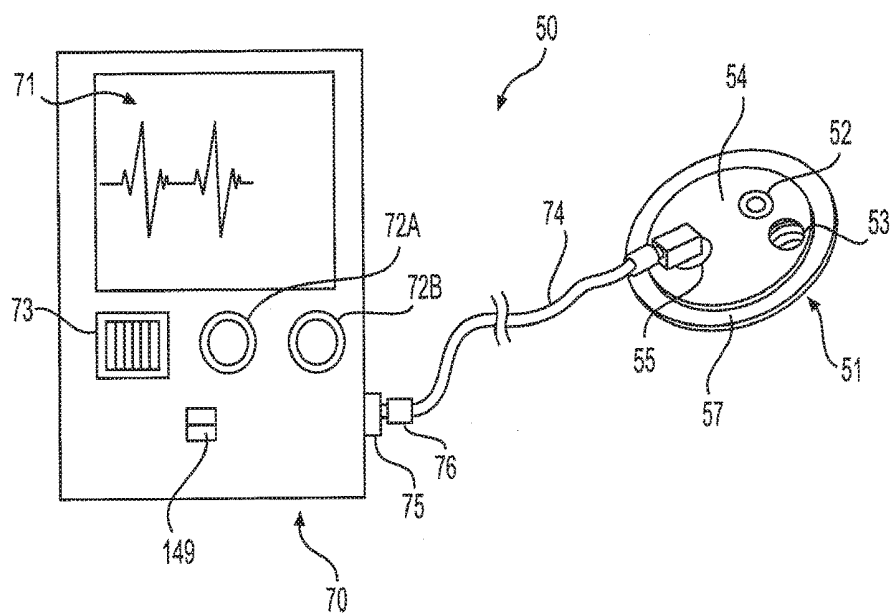
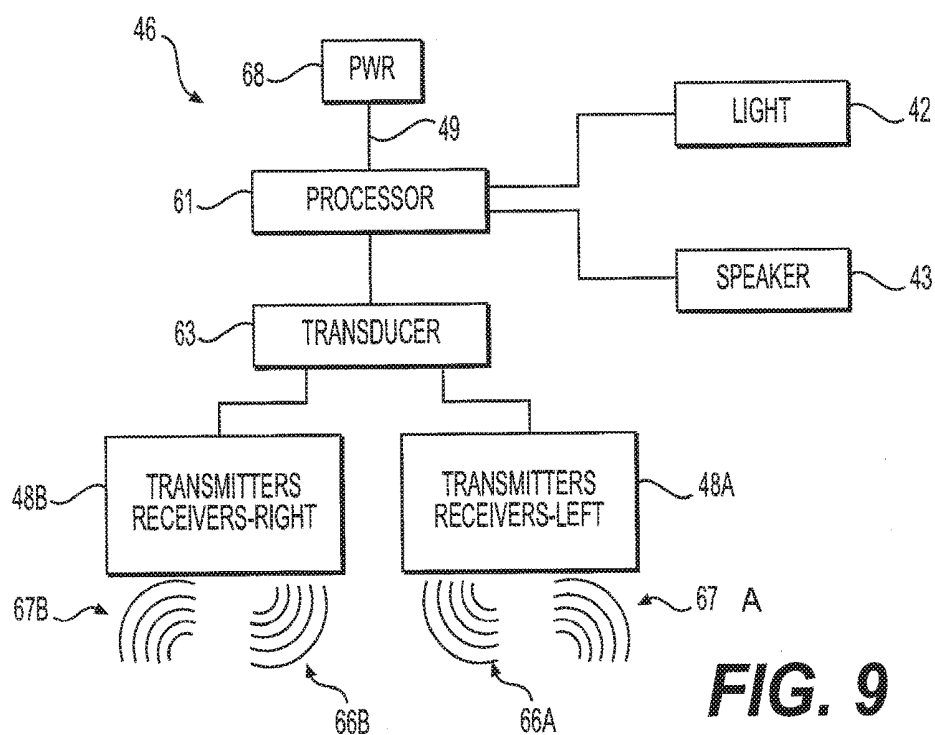


FIG. 12

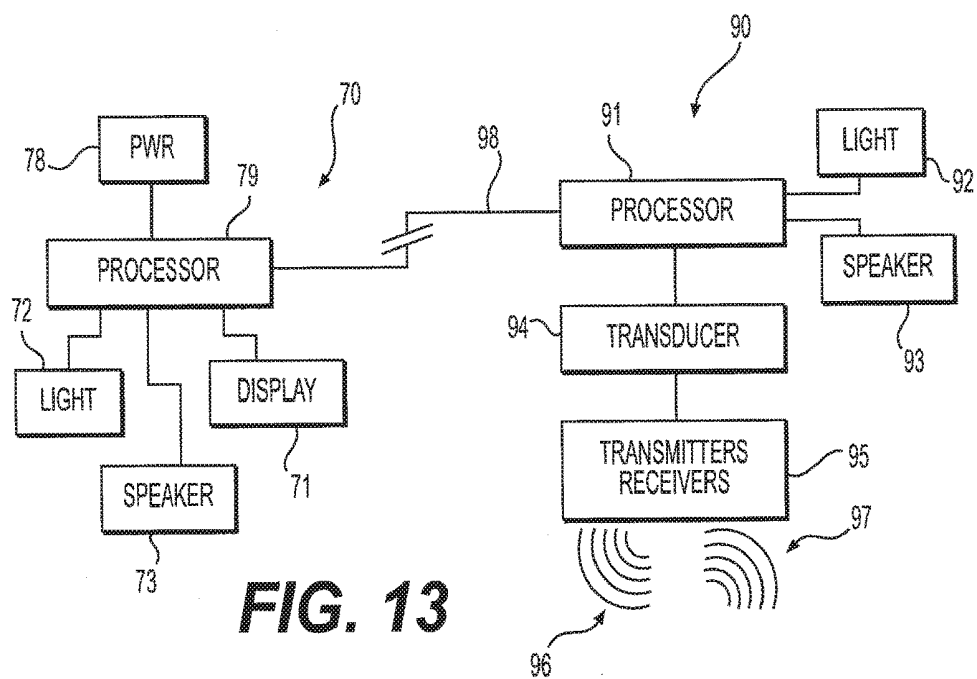


FIG. 13

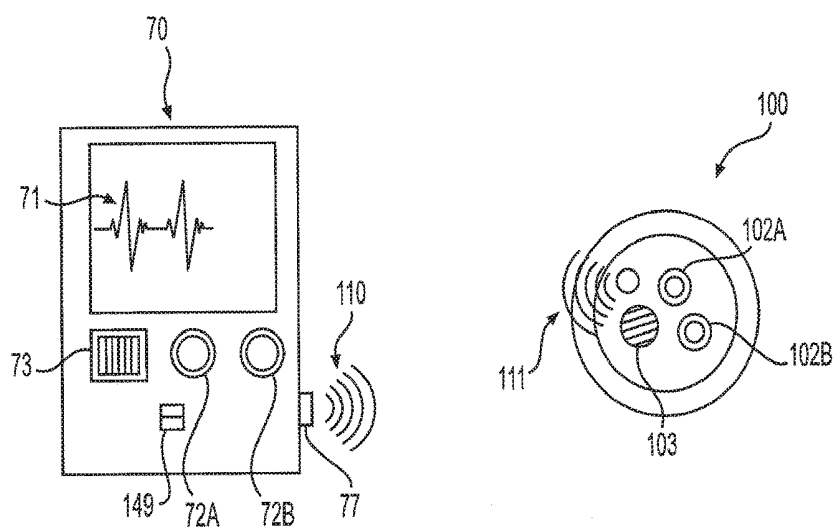


FIG. 14

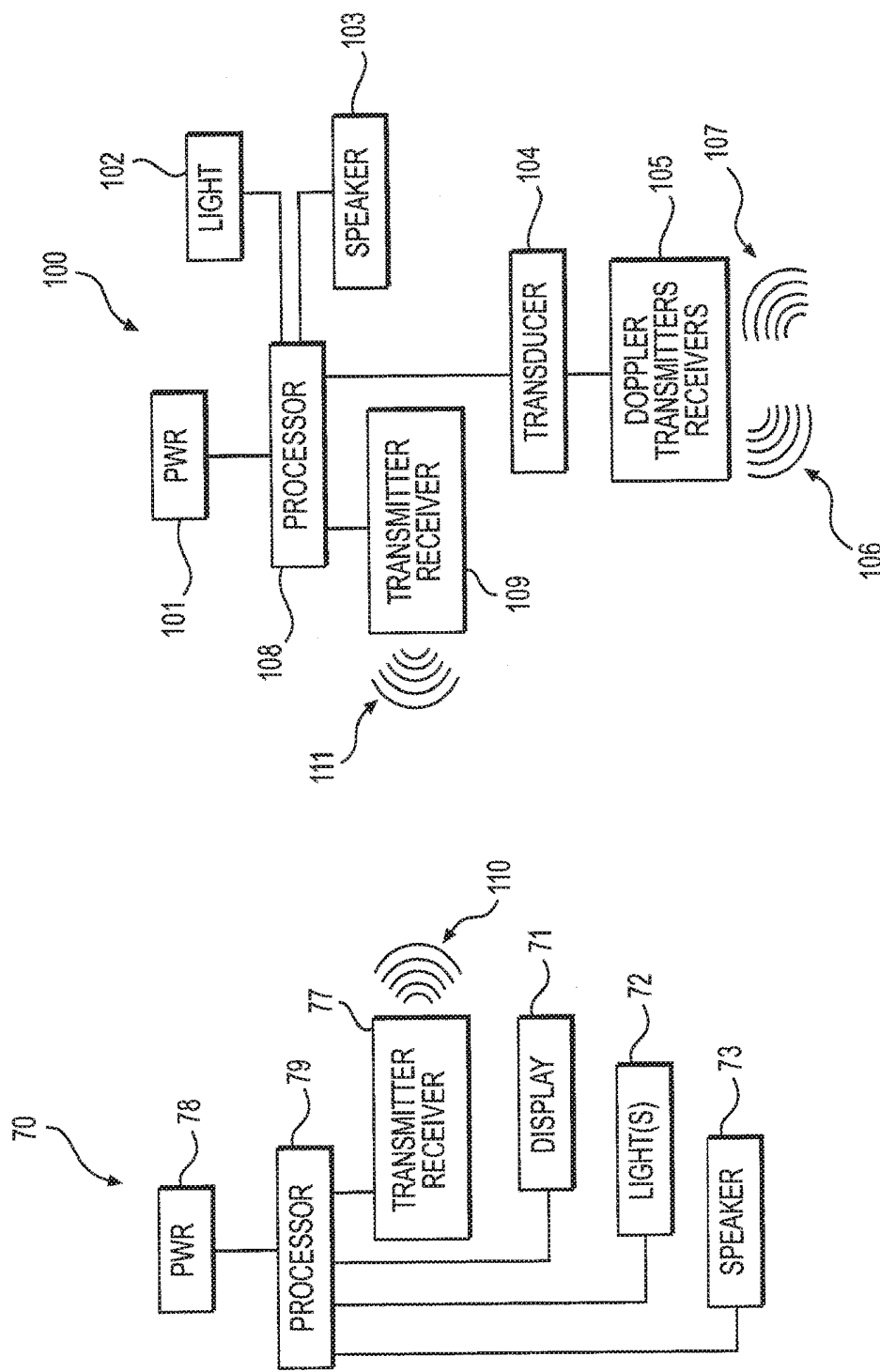


FIG. 15

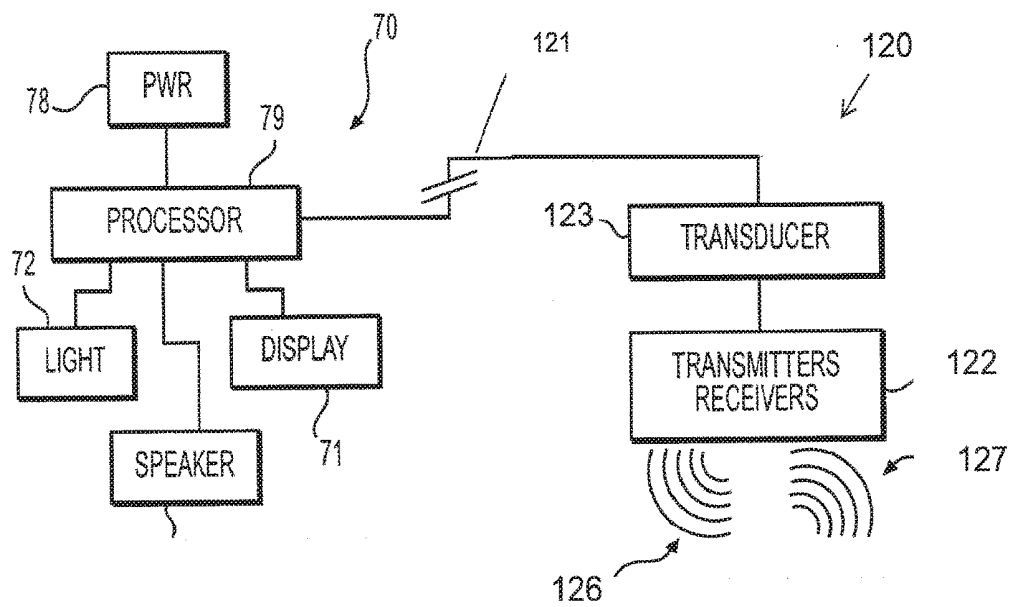


FIG. 16

**STAND-ALONE CONTINUOUS CARDIAC
DOPPLER PULSE MONITORING PATCH
WITH INTEGRAL VISUAL AND AUDITORY
ALERTS, AND PATCH-DISPLAY SYSTEM
AND METHOD**

**CLAIM OF PRIORITY TO PROVISIONAL
APPLICATION (35 U.S.C. § 119(e))**

[0001] This application claims priority under 35 U.S.C. § 119(e) from provisional patent Application No. 62/430,872 filed on Dec. 6, 2016 and from provisional application No. 62/523,765 filed on Jun. 22, 2017. The 62/430,872 and 62/523,765 applications are incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention relates to a stand-alone continuous cardiac Doppler pulse monitoring patch that provides visual and auditory signals that blood flow is detected in a subject. More specifically, the present invention is a small patch that is applied to the skin of a subject, preferably near a large artery, and thereafter generates visual and audible signals indicating the presence or absence of blood flow and, if blood flow is detected, the frequency and strength of the flow. The invention is intended for use by emergency medical technicians, nurses, and doctors as a fast and reliable means to detect a pulse and, if called for, initiate appropriate medical procedures, such as cardiopulmonary resuscitation (CPR).

BACKGROUND OF THE INVENTION

[0003] According to the American Heart Association (http://cpr.heart.org/AHA/ECC/CPRAndECC/General/UCM_477263_Cardiac-Arrest-Statistics.jsp), in the United States, since 2012, over half a million people have experienced cardiac arrest each year. Of those, about sixty percent occurred outside a hospital and almost half of these involved the application of CPR by a lay person. The survival rate for those out-of-hospital cardiac arrests was about ten percent. The survival rate for cardiac arrests in a hospital was also low at under thirty percent. A critical component of surviving cardiac arrest is quick treatment, such as the application of CPR. The decision to initiate CPR or other procedures to treat cardiac arrest is highly time sensitive. The likelihood of survival decreases by ten percent for every minute from the absence of a pulse to the return of spontaneous circulation (ROSC).

[0004] But, the physical palpitation of a pulse, usually by placing one or more fingers over a subject's artery, is difficult and subject to substantial error. In one study, forty-five percent (66 out of 147) of medically trained first responders were unable to identify a pulse despite a carotid pulse and a blood pressure (BP) above or equal to 80 mmHg. Only fifteen percent (31 out of 206) of participants produced a correct diagnosis of the absence of a pulse within ten seconds, which is the recommendation of the American Heart Association.

[0005] The use of an electrocardiograph (ECG) to detect a pulse is common, but problematic, because the widely-recognized graphical pattern measures electrical emissions from the heart muscle. But, these electrical signals detected by the ECG do not measure the flow of blood in the subject and it is not uncommon for telemetry to detect favorable

electrical emissions from the heart, even after the flow of blood has ceased and, in some instances, the subject has perished.

[0006] As noted above, physical palpitation for a pulse is widely used, but is also substantially unreliable. Other means to detect blood flow include Doppler pulse monitors, which have become more common in recent years, especially with the popularity and availability of fetal heart monitors sold at low prices to the general public. These monitors are designed for intermittent checks. A typical Doppler monitor has an ultrasound wand connected to a hand-held box by a cord. A conductive gel, to enhance transmission and reception of the ultrasonic waves, is squirted onto the head of the wand which is placed against the subject. The box amplifies the rhythmic sound of pulsing blood. But, such a device must be held by a technician and cannot be secured in place to provide constant, real-time information. This continuing real-time information is helpful for monitoring dynamic changes in an unstable or potentially unstable patient. For example, when CPR is administered, a hand-held Doppler monitor cannot be held in place without another technician and, even if another technician is available to hold the monitor in place, the movement of the patient undergoing CPR makes holding the wand in place and receiving useful return signals is extremely difficult. Yet, having real-time blood flow information is very helpful to a person performing CPR, because it can inform the technician that CPR has succeeded in achieving ROSC or that the patient is relapsing.

[0007] Even in the hospital setting existing devices pose problems. For example, when a subject requires an X-ray or other scan, existing ECG and Doppler monitors must usually be removed, leaving medical personnel without direct information about the subject's blood flow. As noted above, since the passage of even very short periods of time can drastically reduce the chance of survival from cessation of blood flow, the lack of direct information can be a significant contributor to mortality.

[0008] Identifying and tracking the mechanical blood flow of the heart and large arterial vessels in real time is under-utilized and important. The current system of isolated finger pulse or Doppler pulse checks is challenging, even for medical professionals.

[0009] Needed is a Doppler pulse monitor that is easily and quickly applied to provide constant, real-time detection of a subject's blood flow.

SUMMARY OF THE INVENTION

[0010] The present invention discloses a stand-alone continuous cardiac Doppler pulse monitoring patch that provides visual and auditory signals that a pulse is detected or not detected in a subject. The invention is a small patch with a peel-away adhesive surface that is applied to the skin of a subject, preferably near a large artery. The adhesive surface of the patch includes a conductive medium to enhance transmission and reception of ultrasonic waves. The patch includes a power source, transmitters and receivers to send and detect reflected ultrasonic waves, a transducer to convert an electrical signal into ultrasonic waves and convert the reflected waves into an electrical signal, a processor to control and analyze the signals, a memory, a light to indicate the presence and strength of a pulse, and a speaker also to indicate the presence and strength of a pulse. The Doppler effect of waves reflecting from moving blood or a pulsing

artery is used to detect a pulse in the subject. The presence of a pulse is analyzed by the processor to determine the frequency and strength of blood flow. The processor causes a light to blink at a rate to indicate the frequency of rhythmic blood flow. In a further embodiment, the processor analyzes the strength of the blood flow and causes the light to increase or decrease in intensity to reflect the strength or weakness of the mechanical function of the heart. The processor may also drive a speaker to emit sounds, such as beeps, that indicate the frequency and strength of blood flow. The absence of blood flow may be indicated by the absence of light or sound, or by separate or different light or auditory signals intended to convey the absence of blood flow and potential emergency.

[0011] In an alternative embodiment, the continuous cardiac Doppler pulse monitoring patch can be in the form of a “butterfly” patch designed to straddle a subject’s throat to monitor both left and right carotid arteries. In this butterfly patch embodiment, Doppler ultrasonic signals are transmitted and received from each side of the butterfly patch, one over the left carotid artery and the other over the right carotid artery. The Doppler signals detect the presence or absence of blood flow and pulse from each carotid artery and the information is processed, as described above. The processed flow and pulse information can be displayed visually with a light mounted in the middle of the butterfly patch, over the subject’s throat, as well as audibly with a speaker, as described above. This butterfly patch arrangement can be useful if a cervical collar has been placed around the patient’s neck, because the visual and audible signals of the patch can be seen through the front opening provided in most cervical collars.

[0012] In an alternative embodiment, an integrated continuous cardiac Doppler pulse monitoring patch includes a port to connect the patch by conductive wires to a separate display unit that can receive the blood flow and pulse data from the patch and display the data visually on a screen as well as provide auditory signals. The display unit can further process the data and display heart pulse (bpm) and blood flow (cm/s) rates in numerical and graphic forms. In a further embodiment, the patch and display unit can each include wireless transceivers to connect them and communicate the data wirelessly. In yet a further embodiment, the display unit can provide processing and power for the patch, which is consequently simplified and less expensive. In another embodiment, a simplified patch will have transducers to transmit and receive ultrasound waves and its own integrated power and wireless communication capability, thereby allowing the simplified patch to provide Doppler signal data wirelessly to the display unit, which will process and display the data.

[0013] The invention is intended for use by emergency medical technicians, nurses, and doctors as a fast and reliable means to detect a pulse and, if called for, initiate appropriate medical procedures, such as cardiopulmonary resuscitation (CPR).

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] FIG. 1 shows a stand-alone continuous cardiac Doppler pulse-monitoring patch with visual and auditory alerts of the present invention applied to the neck of a patient.

[0015] FIG. 2 is a side view showing the layers the stand-alone pulse-monitoring patch.

[0016] FIG. 3 is a side, cut-away view showing the arrangement of components of the stand-alone pulse-monitoring patch invention.

[0017] FIG. 4 is a block diagram of the electronic circuitry of the stand-alone pulse-monitoring patch invention.

[0018] FIG. 5 shows a butterfly patch embodiment of the stand-alone pulse-monitoring patch invention applied to the neck of a patient.

[0019] FIG. 6 is a top view of the stand-alone pulse-monitoring butterfly patch invention.

[0020] FIG. 7 is a bottom view of the stand-alone pulse-monitoring butterfly patch invention.

[0021] FIG. 8 is a side, cut-away view showing the arrangement of components of the stand-alone pulse-monitoring butterfly patch invention.

[0022] FIG. 9 is a block diagram of the electronic components of the stand-alone pulse-monitoring butterfly patch invention.

[0023] FIG. 10 is a schematic of a stand-alone pulse-monitoring patch connected by a conductive cable to a display unit.

[0024] FIG. 11 is a side, cut-away view of a stand-alone pulse-monitoring patch with a connector port for the conductive cable connection.

[0025] FIG. 12 is a block diagram of the components of a stand-alone pulse-monitoring patch and a display unit connected by a conductive cable.

[0026] FIG. 13 is a block diagram of the components of an alternate embodiment of a patch connected by a conductive cable to a display unit.

[0027] FIG. 14 is a schematic of a simplified pulse-monitoring patch connected wirelessly to a display unit.

[0028] FIG. 15 is a block diagram of the components of an alternate embodiment of a patch and a display unit connected wirelessly.

[0029] FIG. 16 is a block diagram of the components of an alternate embodiment of a simplified patch and a display unit system.

DETAILED DESCRIPTION

[0030] FIG. 1 shows the stand-alone continuous Doppler heart monitor patch 10 applied to the side of the neck of a patient 5. In this position, the monitor 10 will be close to the subject’s neck artery 6, the right common carotid artery 7B shown in FIG. 5, which is one of the better arteries for detecting a pulse. The carotid artery is a useful position to detect pulse, since it leaves the subject’s chest free for CPR or other procedures to address cardiac arrest. The monitor 10 may be placed over other arteries, such as the femoral or radial arteries. When the on/off switch 19 is turned to the on position, the monitor 10 is placed over the subject’s neck artery 6 and will begin transmitting ultrasonic signals and detecting their reflections. When blood is flowing, the Doppler effect on the reflected signals will be identified by the monitor’s 10 circuitry (16 in FIGS. 2 and 3), described below, as indicative of the blood’s flow velocity, as well as of the frequency of pulses as pulsations of the blood from the heart’s pumps is recognized. This rhythmic pulse will be indicated by a blinking light 12 and may further be indicated by an audible sound, such as a beep, from a speaker 13.

[0031] FIG. 2 illustrates the parts of the monitor patch 10. The bottom of the monitor patch 10 is formed by a base 11, which supports the circuitry 16. Under the base 11 is a conductive pad 14 to enhance transmission and reception of

the ultrasonic waves from the circuitry 16 to the patient 5. The conductive pad 14 may be a thermoplastic gel or a hydrogel. Hydrogels are hydrophilic networks of polymer chains and may be free-standing or contained within a thin membrane. Beneath the conductive pad 14 is a thin adhesive layer 15 to fix the monitor patch 10 to the subject's skin. A peel-off layer 17 is disposed over the adhesive layer 15 to cover and preserve the adhesive until used. Mounted on the base 11 is the circuitry 16, described below. The circuitry 16 may be mounted on a printed circuit board (PCB), which may be rigid, but, in a preferred embodiment, has some flexibility to conform to the subject's body contours. Over the circuitry 16 are a light 12 and a speaker 13 and, in some embodiments, a manual on/off switch 19. A conductor 29 from the circuitry 16 to the light 12 allows electricity to flow to the light 12. Similarly, a conductor 30 controls electrical flow to the speaker 13, and conductors 31 provide connectivity between the on/off switch 19 on the circuitry 16.

[0032] FIGS. 3 and 4 show more detail of the circuitry 16. A power source 28, such as a small battery, provides integrated power to the electronic components of the standalone monitor patch 10. A switch 32 controls power or can activate the circuitry 16 from a low-power consumption rest state. A transducer 23 includes transmitters/receivers 18 arrayed in or over the base 11. The transmitters emit ultrasonic waves 26 and the receivers detect reflected waves 27. The reflected wave signals 27 are demodulated and analyzed by a processor 21 to determine whether the reflected wave pattern corresponds with Doppler shift signals indicative of flowing blood. Since blood from a heart is pumped in rhythmic pulses, the received Doppler shift signals will indicate that pattern. The processor 21 incorporates memory that can include data of Doppler shift signals indicative of flowing or pulsing blood. By comparing the Doppler shift signals 27 from the transducer 23 with data stored in the memory associated with the processor 21, the processor determines whether blood flow has been detected. Once a blood flow is detected, the processor 21 causes a light 12 (24 in FIG. 4) to blink in synchronization with the rhythm of the heart's pulses. Similarly, the processor 21 will cause a speaker 13 (25 in FIG. 4) to emit a sound, such as a beep, in synchronization with the rhythm of the heart's pulses. The processor 21 will also analyze the reflected wave signals 27 for their strength by comparing them to known values stored in the processor's 21 memory. Using the stored values, the processor 21 will cause the light 12 to blink with an intensity corresponding to the strength or weakness of the detected pulse. Similarly, based on the stored values, the processor 21 will cause the speaker 13 to beep with a volume corresponding to the strength or weakness of the detected pulse.

[0033] The light 12 may be an LED. In a preferred embodiment, the LED light 12 is capable of emitting different colors of light, such as red and green. For example, if a healthy pulse is detected by the monitor patch 10, the processor 21 will cause the light 12 to blink with a green color indicating a healthy pulse, but if a weak pulse is detected, the processor 21 will cause the light 12 to emit a yellow or red color. Alternatively, two or more lights 12 may be employed, each chosen to emit a different color. As described above, the processor 21, relying on values stored in the processor's memory, will cause the intensity of the light to increase or decrease, or the color of the light to change, in relation to the strength or weakness of the detected pulse. Similarly, the processor 21 will cause the

speaker 13 to increase or decrease the volume, or change another characteristic of the emitted sound in relation to the strength or weakness of the detected pulse. If the processor 21 detects a weak or declining pulse, the processor 21 will cause a color-changing LED light 12 to change in color, for example from green to red, or will shift the visual indicator from one color (e.g., green) light to a different color (e.g., yellow or red) light. Similarly, the processor 21 may cause the speaker 13 to emit a different sound as a weak or declining pulse is detected. If a pulse is lost, the processor 21 can cause a color-changing LED light 12, or a separate light, to emit a continuous bright, emergency red light. Similarly, if no pulse is detected or if a pulse signal fades completely, the processor 21 may cause the speaker 13 to emit a shrill continuous emergency sound.

[0034] In operation, the continuous cardiac Doppler monitor patch 10 will be applied to a patient 5 when a continuous pulse needs to be identified. The monitor patch 10 is activated or turned on by a switch 19, the peel-off layer 17 is removed, exposing the adhesive 15, and the monitor patch 10 is placed over a subject's 5 artery 6. It will be appreciated that the sequence of activating the switch 19 and removing the peel-off layer 17 may be reversed. In an alternative embodiment, the removal of the peel-off layer 17 will turn on or activate the circuitry 16 of the monitor patch 10, either by turning a switch 19 to the active "on" position or by closing the on/off circuit 32 to the power source 28. By deactivating the circuitry 16 of the monitor patch 10, or cutting off power from the power source 28, the switch 19 allows the monitor patch 10 to be inactive for long periods of time, such as during storage, yet be available in an instant when needed. When the monitor patch 10 is turned on, the processor 21 will direct the transducer 23 to send and receive ultrasonic signals, 26 and 27, from the transmitters/receivers 18. The transmitted and received signals, 26 and 27, may be combined, or the reflected signals 27 alone may be analyzed by the processor 21 and compared to values stored in the processor's 21 memory. If the combined, 16 and 27, or reflected signals 27 correspond to a stored value for blood pumped by a heart, the processor 21 will cause the light 12 to blink in synchronization with the pulse and with an intensity corresponding to the strength or weakness of the pulse. Similarly, the processor 21 will cause the speaker 13 to beep in synchronization with the pulse and with a volume corresponding to the strength or weakness of the pulse.

[0035] The monitor patch 10 may be used on unstable patients or patients with the potential of instability. Identifying the absence of a pulse is paramount to initiating CPR. The monitor patch 10 can also be applied while patients 5 are in motion. For example, moving patients 5 down stairs or transporting patients 5 in a helicopter. Moving patients 5 downstairs requires that the transporting personnel be at the head and foot of the stretcher, where they are unable to verify a continuous pulse. Similarly, air medical evacuations, and even automotive transportation, are loud and vibrations distracting, interfering with the detection of a pulse. For example, it is difficult to feel a pulse or auscultate a heart beat in a helicopter. The monitor patch 10 uses a light 12 as proof of a heart beat and pulse. Moreover, in low visibility environments, the monitor patch 10 uses a speaker 13 as proof of a heart beat and pulse.

[0036] The monitor patch 10 will, preferably, be placed on a large artery 6, such as the carotid, radial, or femoral arteries. The monitor patch 10 can be also located on the

chest wall, since the ejection of blood from the aortic valve can be captured by the reflected Doppler signal 27. Ideally, the monitor patch 10 will be placed on the patient's 5 left carotid artery 6 (7A in FIG. 4). The left carotid will be the most common site of placement because of infrequent procedural use, a large pulse wave, and its location away from the patient's 5 chest. The chest is needed for ECGs, defibrillator pads, and chest compressions. The monitor patch 10 of the present invention is designed as a stand-alone that integrates the switch 19, light 12, speaker 13, circuitry 16, base 11, conductive pad 14, and adhesive layer 15 into a unitary and compact device configured to conform and adhere to the contours of a subject's 5 skin above an artery 6. Ideally, a small patch of about 2½ inches in diameter, or about 5 square inches, will conform easily to the contours of the patient's skin and reside over an area where arterial blood may be detected. Stand-alone monitor patches of the invention may be larger to provide more space for circuitry and cover greater area over an artery; such stand-alone monitor patches are not limited in size, but a larger patch will be cumbersome and difficult to apply. It is preferred, but not required that stand-alone monitor patches cover areas of less than about twenty square inches.

[0037] The monitor patch 10 will be able to generate visual 12 and auditory 13 signals. The signal will increase and decrease in intensity based on the pulse wave generated by the heart. This enables the medical provider to determine if the patient's 5 pulse is strong, weak, or absent. The signals (light & sound) also vary in intensity with a diminishing or increased pulse wave. This enables the medical provider to determine if a pulse is weakening or stopping and the provider will be able to take appropriate actions and determine if a treatment is working by an increased pulse signal.

[0038] The monitor patch 10 of the present invention can monitor dynamic changes in unstable or potentially unstable patients. With this information the medical provider can use the intensity of the light/sound signal to closely follow the pulse wave and manage therapy in real time. This feature is especially helpful in evaluating the effectiveness of CPR. A strong signal will signify adequate CPR, improving success to Return of Spontaneous Circulation (ROSC).

[0039] The monitor patch 10 can also detect blood flow to an extremity, thereby providing information about the exact time of ischemia (inadequate blood flow) or changes in blood flow. This can be used to monitor for compartment syndrome, violation of the neurovascular bundle, or an embolic event to a large extremity.

[0040] The invention also provides a simple continuous cardiac Doppler monitor patch 10 for checking fetal distress in pregnancy.

[0041] FIGS. 5 through 9 show an alternative embodiment of the stand-alone continuous cardiac Doppler pulse monitoring patch that provides visual and auditory signals that a pulse is detected or not detected in a subject. In this embodiment, the patch 40 is shaped in a "butterfly" configuration to straddle a subject's throat so that each wing, 41A and 41B, covers that part of the throat over the left 7A and right 7B carotid arteries. In this position, the monitor 40 detects a pulse from either the left 7A or right 7B carotid arteries or both. As noted previously, the carotid artery is a useful position to detect pulse, since it leaves the subject's chest free for CPR or other procedures to address cardiac arrest. The butterfly monitor patch 40 may be placed over other arteries, such as the femoral or radial arteries. Each

wing, 41A at the left and 41B at the right, of the butterfly patch 40 includes an array of transmitters/receivers, 48A and 48B, respectively. As described above, the transmitters of each array, 48A and 48B, emit ultrasonic waves, 66A at the left and 66B at the right, and the receivers, 67A at the left and 67B at the right, detect reflected waves. The reflected wave signals, 67A and 67B, are demodulated and analyzed by a processor 61 to determine whether the reflected wave pattern corresponds with Doppler shift signals indicative of flowing blood, as described above. Since blood from a heart is pumped in rhythmic pulses, the received Doppler shift signals will indicate that pattern and the memory in association with the processor 61 will provide data of models indicative of heart pulse patterns. Once a blood flow is detected, the processor 61 may cause a light 42 to emit light or blink in synchronization with the rhythm of the heart's pulses. Similarly, the processor 61 may cause a speaker 43 to emit a sound, such as a beep, in synchronization with the rhythm of the heart's pulses. As noted above, the processor 61 will also analyze the reflected wave signals, 67A and 67B, for their strength by comparing them to known values stored in the processor's 61 memory. Using the stored values, the processor 61 will cause the light 42 to blink with an intensity corresponding to the strength or weakness of the detected pulse. Similarly, based on the stored values, the processor 61 will cause the speaker 43 to beep with a volume corresponding to the strength or weakness of the detected pulse.

[0042] The butterfly patch 40 is placed over the front of the subject's 5 neck 6 so that the left wing 41A is over the left carotid artery 7A and the right wing 41B is over the right carotid artery 7B. The butterfly patch 40 can include an on/off switch 49, or it can be turned on in some other manner, such as removal of the peel-away layer 47, as described above. Alternatively, the butterfly patch 40 could be connected through a port 55 by a conductive cable 74, such as the arrangement shown in FIG. 10 and described below, to a separate display unit 70, which can turn the butterfly patch 40 on or off. Once on, the Doppler transmitters and receivers, 48A and 48B, will begin transmitting ultrasonic signals, 66A and 66B, and receiving their reflections, 67A and 67B. When blood is flowing, the Doppler effect on the reflected signals will be identified by the monitor's 40 circuitry 46, described below, as indicative of the blood's flow velocity, as well as of the frequency of pulses as pulsations of the blood from the heart's pumps is recognized. This rhythmic pulse will be indicated by a blinking light 42 and may further be indicated by an audible sound from a speaker 43.

[0043] In a preferred embodiment, the butterfly monitor patch 40 is designed for use with a cervical collar ("C-collar", not shown) around the subject's 5 neck 6, which is common practice in emergency conditions, and in which situations the detection of a pulse is of great importance to medical personnel. To adapt the patch 40 for such use, it should be flat so that a C-collar will fit over the patch 40. Many C-collars include a front opening that exposes the subject's 5 trachea. The light 42, speaker 43, on/off switch 49, and connector port 55 may be located on the middle portion 41C of the butterfly patch 40, so as to be accessible and visible through the C-collar's tracheal opening. If the patch 40 is connected by a cable 74 to a separate unit 70, the cable 74 can reach the patch 40 through the C-collar's tracheal opening.

[0044] FIG. 8 illustrates the parts of the butterfly monitor patch 40. A base 41 supports circuitry 46. Under the base 41 is a conductive pad 44 to enhance transmission and reception of the ultrasonic waves from the circuitry 46 to the patient. As described above, the conductive pad 44 may be a thermoplastic gel or a hydrogel. Hydrogels are hydrophilic networks of polymer chains and may be free-standing or contained within a thin membrane. Beneath the conductive pad 44 is a thin adhesive layer 45 to fix the patch 40 to the subject's 5 skin. A peel-off layer 47 is disposed over the adhesive layer 45 to cover and preserve the adhesive until used. Mounted on the base 41 is the circuitry 46, described below. The circuitry 46 may be mounted on a printed circuit board (PCB), which may be rigid, but, in a preferred embodiment, has some flexibility to conform to the subject's body. The monitor patch 40 may include a light 42, speaker 43, and a switch 49. The switch 49 may turn the patch 40 on or off by activating the circuitry 46, disconnecting power from the power source 68, or the switch 49 may have additional settings. Thus, the switch 49 may turn on the processor 61 and transmitters/receivers, 48A and 48B, and cause the light 42 and speaker 43 to indicate the presence or absence of a pulse, as well as the strength of the pulse, as described above. Or, the switch 49 may have a setting to turn on the light 42 but keep the speaker 43 off, so that the subject's 5 rest is not disturbed. Or, the switch 49 may turn off both the light 42 and the speaker 43 and transmit the pulse data over the cable 74 to a separate display unit 70 (shown in FIG. 10), where the pulse can be indicated by the display unit's 70 light 72A, speaker 73, or graphic display 71. By removing the pulse light and speaker signals from the subject 5 to a remotely located display unit 70, the subject 5 is allowed to rest undisturbed. Similarly, a subject's 5 cardiac status can be monitored at a distance when the subject 5 is not physically near medical personnel, such as when a subject 5 is trapped in a dangerous location or undergoing treatment, such as X-rays or MRI, where medical personnel must remain at a distance.

[0045] FIGS. 8 and 9 show more detail of the circuitry 46 of the butterfly patch monitor 40. A power source 68, such as a small battery, provides integrated power to the electronic components. An on/off switch 49 on the patch 40 can be used to activate the circuitry 46 of the patch 40. As with the previous embodiment, alternative mechanical or electronic switching arrangements may be employed, such as a mechanical switch that activates the circuitry 46 when the peel-away layer 47 is removed. A transducer 63 includes transmitters/receivers, 48A and 48B, arrayed in or over the base 41. The transmitters emit ultrasonic waves, 66A and 66B, and the receivers detect reflected waves, 67A and 67B. The reflected wave signals, 67A and 67B, are demodulated and analyzed by a processor 61, or the transmitted ultrasonic wave signals may be combined with the demodulated reflected wave signals, 67A and 67B, for analysis by the processor 61, to determine whether the reflected wave patterns correspond with Doppler shift signals indicative of flowing blood. Since blood from a heart is pumped in rhythmic pulses, the received Doppler shift signals will indicate that pattern, as described above. Once blood flow is detected, the processor 61 causes a light 42 to blink in synchronization with the rhythm of the heart's pulses. Similarly, the processor 61 will cause a speaker 43 to emit a sound, such as a beep, in synchronization with the rhythm of the heart's pulses. The processor 61 will also analyze the

reflected wave signals, 67A and 67B, for their strength by comparing them to known values stored in the processor's 61 memory. Using the stored values, the processor 61 will cause the light 42 to blink with an intensity corresponding to the strength or weakness of the detected pulse. As with the previous embodiment, the light 42 may be a single LED light source capable providing different colors or varying intensities of brightness, or more than one light may be used to accomplish this, and, if no pulse is detected or if a detected pulse fades away, an emergency alarm light, such as a bright red light, may be activated. Similarly, based on the stored values, the processor 61 will cause the speaker 43 to beep in with a volume corresponding to the strength or weakness of the detected pulse and, if no pulse is detected or if a pulse signal fades completely, the processor 61 may cause the speaker 43 to emit a shrill continuous sound.

[0046] Referring FIGS. 10 through 12, in an alternative embodiment, a stand-alone continuous cardiac Doppler pulse monitoring patch 51 is connected by one or more conductive data cables 74 to a remote display unit 70. In this embodiment, a patient's blood flow and pulse can be remotely monitored by medical personnel. This capability allows medical personnel to monitor a subject's blood flow remotely when the subject is undergoing procedures, such as X-ray or an MRI, where the light 52 on the patch 51 cannot be seen or the speaker 53 cannot be heard, or when the subject is located in a dangerous area, such as a collapsed building. Also, when a subject is resting, it is possible to turn off the speaker 53 and light 52 on the patch 50 to prevent disturbing the patient, yet continue to monitor the subject's blood flow remotely from the display unit 70. By providing a data cable 74, it is also possible to download data from the memory of the processor 81 of the patch 51. In this way, the patch 51 can store detected cardiac pulse data, which can be downloaded via the data cable 74 to the display unit 70 or a separate computing device and later analyzed. For example, when emergency medical technicians reach a subject, the stand-alone monitor patch 51 (or the butterfly monitor patch 40 or the wireless monitor patch 90) is activated, applied to the subject, detects a pulse, and the memory in association with the processor 81 begins saving data of the subject's pulse. Later, for example, when the subject reaches hospital, the stand-alone monitor patch 51 (or the butterfly monitor patch 40 or the wireless monitor patch 90) is connected by a data cable 74 to the display unit 70 or a separate computing device and the subject's historical pulse data may be analyzed to evaluate the heart's behavior from the time the monitor patch was applied.

[0047] To accommodate this system 50, the patch 51 includes a port 55 that may receive one or more connectors 76 of one or more conductive cables 74. As noted above, the patch 51 is formed by a base 54, which supports the circuitry 56. The circuitry 56 includes transmitter and receiver units 58 on or incorporated into the base 54. Under the base 54 is a conductive pad 57, as described above. Beneath the conductive pad 57 is a thin adhesive layer 59 to fix the monitor patch 51 to the subject's skin. A peel-off layer 60 is disposed over the adhesive layer 59. Mounted on the base 54 is the circuitry 56, described below. The circuitry 56 may be mounted on a printed circuit board (PCB), which may be rigid, but, in a preferred embodiment, has some flexibility to conform to the subject's body. Over the circuitry 56 are one or more lights 52 and a speaker 53 and, in some embodiments, a manual on/off switch may be included, such as has

been described above. The port 55 shown in FIGS. 10 and 11 is directed to receive a connector 76 from the side, along the plane of the base 54, which is a preferred orientation when the patch 51 is placed over one of the subject's carotid artery, so that the cable 74 will not project away from the neck, which could interfere with a C-collar or present an obstruction to the subject and medical personnel. In contrast, the butterfly monitor patch 40 shown in FIGS. 5 through 9 has a connector port 55 in the middle portion 41C directed to receive the connector 76 from above, normal to the plane of the base 41, which places the light 42, speaker 43, switch 49, connector port 55, and cable 74 within the tracheal opening provided in many cervical collars. The embodiments shown have a single port 55, connector 76 and cable 74, but multiple ports and cable connectors could be accommodated.

[0048] The cable 74 connects to the remote display unit 70 through a port 75. The cable 74 may be permanently connected to the display unit 70 or the cable may have a connector 76 so that it may be disconnected. In the embodiment shown in FIG. 10, the display unit 70 has two lights, 72A and 72B, so that the heart rhythm and flow strength can be indicated on one light or light cluster 72A and an emergency light indicator 72B can show that the subject's heart has stopped pumping blood or is dangerously close to doing so. The display unit 70 also has a speaker 73 to provide an audible indicator the subject's heart rhythm and strength, and the speaker may also provide an emergency sound to indicate that the subject's heart is or has failed. The unit 70 may also include a graphic display screen 71 to provide textual, numerical and graphical information about the subject's blood flow, such as a numerical display of heart rate (bpm) and blood velocity (cm/s), as well as a waveform to show the strength of the subject's pulse, pressure, and blood velocity over time. A switch 149 is provided to turn the display unit 70 on or off.

[0049] Referring to FIGS. 11 and 12, in one embodiment, the stand-alone monitor patch 51 has its own power source 80, such as a small battery, to provide integrated power to the electronic components. A switch, as in previously disclosed embodiments may also be incorporated into the patch 51. A transducer 84 includes transmitters/receivers 85 (shown as units 58 in FIG. 12) arrayed in or over the base 54. The transmitters emit ultrasonic waves 86 and the receivers detect reflected waves 87. As described above, the reflected wave signals 87 are demodulated and analyzed by a processor 81 to determine whether the reflected wave pattern corresponds with Doppler shift signals indicative of flowing blood. Once a blood flow is detected, the processor 81 causes the light 52 to blink in synchronization with the rhythm of the heart's pulses. Similarly, the processor 81 will cause a speaker 53 to emit a sound, a beep, in synchronization with the rhythm of the heart's pulses. The processor 81 will also analyze the reflected wave signals 87 for their strength by comparing them to known values stored in the processor's 81 memory. Using the stored values, the processor 81 will cause the light or lights 52 to blink with an intensity corresponding to the strength or weakness of the detected pulse. Similarly, based on the stored values, the processor 81 will cause the speaker 53 to beep in with a volume corresponding to the strength or weakness of the detected pulse.

[0050] The patch 51 is connected to the display unit 70 by cable 74, as previously disclosed. The display unit 70 has its

own power source 78 to power its components. The display unit's 70 processor 79 receives the heart flow and velocity data from the patch 51 and causes one or more lights 72A to display the pulse in the manner described above. A no-pulse light 72B can provide a visual signal that the subject's pulse has failed. A speaker 73 can emit sounds to provide audible signals of the subject's pulse. A display 71 provides textual, numerical and graphical information about the subject's blood flow, such as a numerical display of pulse rate (bpm) and blood velocity (cm/s), as well as a waveform to show the strength of the subject's pulse, pressure, and blood velocity over time. The processor's 79 memory can store data of the subject's cardiac status over time by downloading such data from the stand-alone monitor patch 51 processor's 81 memory and from the display unit's 70 processor's 79 memory, and this historical data may be displayed on the unit's 70 screen 71 or transmitted to other medical equipment for analysis.

[0051] Referring to FIG. 13, an alternative embodiment is disclosed whereby a remote display unit 70 includes a power source 78 to provide power to a monitor patch 90 over a power and data cable 98 to power the patch components, such as the processor 91, transducer 94, transmitters/receivers 95, light(s) 92, and speaker 93. The display unit 70 is a compact, hand-held box, capable of accommodating more battery power, processing, and memory, and display options than the patch 90 can provide. In a basic embodiment, the unit 70 is very compact and includes only one indicator of the subject's blood flow, such as the light 72.

[0052] Referring to FIGS. 14 and 15, an alternative embodiment is disclosed whereby the stand-alone monitor patch 100 transmits 111 and receives 100 wireless data signals from the remote display unit 70. In this embodiment, the patch 100 includes its own power source 101 and transmitter/receiver 109. The display unit 70 also has a transmitter/receiver 77 to receive and send data to the patch 50.

[0053] Referring to FIG. 16, another alternative embodiment is disclosed whereby the display unit 70 provides power from a power source 78 and processing from a processor 79 via a power and data cable 121 to a simplified monitor patch 120 to power the transducer 123 and transmitters/receivers 122, which operate as described above. The simplified monitor patch 120 is less expensive to make, since it has fewer components, and may be discarded after use, while the display unit 70 may be re-used.

[0054] The drawings and description set forth here represent only some embodiments of the invention. After considering these, skilled persons will understand that there are many ways to make a continuous Doppler cardiac pulse monitor patch according to the principles disclosed. The inventor contemplates that the use of alternative structures, materials, or manufacturing techniques, which result in a monitor patch according to the principles disclosed, will be within the scope of the invention.

1. A stand-alone continuous Doppler heart monitor patch comprising:

- a base having an upper base surface and a lower base surface on a side opposite the upper base surface,
- circuitry disposed on the upper base surface, the circuitry comprising at least one transducer configured to transmit ultrasound waves in a direction beyond the lower base surface and receive reflected ultrasound waves, a digital to analog converter for converting transmitted

digital ultrasound wave signals from a processor to converted ultrasound waves and delivering the converted ultrasound waves to the transducer, an analog to digital converter for converting reflected ultrasound waves from the transducer to reflected digital ultrasound wave signals and delivering the reflected digital ultrasound wave signals to the processor, a power source providing power to the circuitry, and memory in association with the processor, wherein the processor delivers the transmitted digital ultrasound wave signals to the digital to analog converter and controls transmission of ultrasound waves by the transducer, and wherein the processor processes the reflected digital ultrasound wave signals,

a pad formed of sound conducting gel, the pad having an upper pad surface and a lower pad surface opposite to the upper pad surface, wherein the upper pad surface is disposed on the lower base surface,

an adhesive layer having an upper adhesive surface and a lower adhesive surface opposite the upper adhesive surface, wherein the upper adhesive surface is disposed on the lower pad surface, and wherein the lower adhesive surface is adapted to adhere releaseably to skin of a human,

a peel-away sheet disposed on the lower adhesive surface, wherein the peel-away sheet is removable from the lower adhesive surface to expose the lower adhesive surface, and

wherein the patch is adapted and to conform to a contour of the skin over an artery and the patch is sized to fit on the skin over a portion of the artery, wherein the processor is adapted to detect a detected blood pulse in the artery from the transmitted digital ultrasound wave signals and the reflected digital ultrasound wave signals, wherein the processor causes a blood pulse signal to be emitted indicative of the detected blood pulse in the artery, and wherein the base, circuitry, pad, adhesive layer, and peel-away sheet are integrated into the patch and the patch is capable monitoring the detected blood pulse and emitting the blood pulse signal independent of any external device.

2. The stand-alone continuous Doppler heart monitor patch of claim 1 wherein the blood pulse signal comprises a light source to emit light in response to the detected blood pulse.

3. The stand-alone continuous Doppler heart monitor patch of claim 2 wherein the light emitted in response to the detected blood pulse comprises a variable light intensity proportional to a strength of the detected blood pulse, and wherein the light emitted in response to the detected blood pulse further comprises an emergency light activated when the processor detects an absence of the detected blood pulse in the artery.

4. The stand-alone continuous Doppler heart monitor patch of claim 3 wherein the blood pulse signal comprises a speaker to emit sound in response to the detected blood pulse.

5. The stand-alone continuous Doppler heart monitor patch of claim 4 wherein the sound emitted in response to the detected blood pulse comprises a variable sound intensity proportional to the strength of the detected blood pulse, and wherein the sound emitted in response to the detected

blood pulse further comprises an emergency sound activated when the processor detects an absence of the detected blood pulse in the artery.

6. The stand-alone continuous Doppler heart monitor patch of claim 4 further comprising a switch to activate the circuitry from an inactive state.

7. The stand-alone continuous Doppler heart monitor patch of claim 6 wherein the switch is activated when the peel-away sheet is removed from the lower adhesive surface.

8. The stand-alone continuous Doppler heart monitor patch of claim 1 wherein the circuitry is incorporated onto a printed circuit board and wherein the base and the printed circuit board are flexible.

9. The stand-alone continuous Doppler heart monitor patch of claim 1 further comprising a connector port for communicating data from the patch to an external device.

10. The stand-alone continuous Doppler heart monitor patch of claim 9 further comprising a conductive cable received by the connector port and wherein the conductive cable communicates the data from the patch to the external device.

11. The stand-alone continuous Doppler heart monitor patch of claim 9 wherein the connector port comprises a wireless transceiver for communicating the data from the patch to the external device.

12. The stand-alone continuous Doppler heart monitor patch of claim 9 wherein the external device comprises a display unit comprising at least one display unit light source, a display unit speaker, and a graphic display, wherein the display unit light source emits light in response to the detected blood pulse, the display unit speaker emits sound in response to the detected blood pulse, and the graphic display provides a graphical display of blood pulse over time of the detected pulse.

13. The stand-alone continuous Doppler heart monitor patch of claim 9 wherein the memory in association with the processor stores blood pulse data of the detected blood pulse over time, and wherein the blood pulse data may be accessed by the external device via the connector port.

14. The stand-alone continuous Doppler heart monitor patch of claim 1 further comprising

a second base having a second upper base surface and a second lower base surface opposite the second upper base surface,

at least one second base transducer configured to transmit second base ultrasound waves in a second base direction beyond the second lower base surface and receive second base reflected ultrasound waves, wherein the second base transducer is disposed on the second upper base surface, and wherein the processor is further adapted to detect the detected blood pulse in the artery from the second base transmitted ultrasound waves and the second base reflected ultrasound waves,

a second base pad formed of sound conducting gel, the second base pad having a second base upper pad surface and a second base lower pad surface opposite the second base upper pad surface, wherein the second base upper pad surface is disposed on the second base lower base surface,

a second base adhesive layer having a second base upper adhesive surface and a second base lower adhesive surface opposite the second base upper surface, where the second base upper adhesive surface is disposed on

the second base lower pad surface, and wherein the second base adhesive layer is adapted to adhere to skin of a human,

a second base peel-away sheet disposed on the second base lower adhesive surface, wherein the second base peel-away sheet is removable from the second base lower adhesive surface to expose the second base adhesive layer, and

wherein the patch is further adapted and sized to fit and conform to the contour of the skin of a neck so that the base is located over one of the left or right carotid arteries and the second base is located over an other of the of the left or right carotid arteries.

15. The stand-alone continuous Doppler heart monitor patch of claim **14** wherein the blood pulse signal of the patch is located between the base and the second base over the neck between the left and right carotid arteries and the pulse signal is further located to be observable through an opening in a cervical collar.

16. A continuous Doppler heart monitor patch and display unit system comprising:

a patch configured to adhere to skin over an artery of a patient, the patch comprising a conductive gel layer forming a surface of the patch, an adhesive layer disposed on the surface and adapted to adhere the patch to the skin of the patient, a plurality of transducers for transmitting ultrasound waves through the conductive gel and adhesive layers and for receiving reflected ultrasound waves, and a conductive cable in electrical communication with the plurality of transducers, and

a portable display unit comprising a port for receiving the conductive cable, a digital to analog converter, an analog to digital converter, a processor, memory, a blood pulse display, and a power source, wherein the processor transmits ultrasound wave digital signals to the digital to analog converter, the digital to analog converter converts the ultrasound wave digital signals from the processor to converted ultrasound waves and transmits the converted ultrasound waves over the conductive cable to the plurality of transducers in the patch, the analog to digital converter receives the reflected ultrasound waves from the plurality of transducers in the patch over the conductive cable, the analog to digital converter converts the reflected ultrasound waves to reflected ultrasound wave digital signals and transmits the reflected ultrasound wave digital signals to the processor, the processor processes the ultrasound wave digital signals and reflected ultrasound wave signals to detect blood flow in the artery of the patient, and the processor causes the blood pulse display to emit an observable signal corresponding to the blood flow.

17. The continuous Doppler heart monitor patch and display unit system of claim **16** wherein the blood pulse display comprises a light source, a speaker, and a screen, wherein the light source is configured to emit light corresponding to the blood flow, the speaker is configured to emit sound corresponding to the blood flow, and the screen is configured to provide a graphic visual display of a pulse

frequency of the blood flow, and wherein one or more of the light source, speaker, and screen may be activated or deactivated.

18. A method of monitoring blood flow in a patient comprising the steps of:

providing a stand-alone continuous cardiac Doppler patch configured to conform to contours of skin over an artery of a patient and wherein the patch is limited to a size under twenty square inches and to fit over a portion of the artery, the patch comprising a base, an adhesive layer having an upper adhesive surface and a lower adhesive surface opposite the upper adhesive surface, the lower adhesive surface adapted to adhere releaseably to the patient's skin, wherein the upper adhesive surface is disposed on a lower surface of the base, a peel-away sheet covering the lower adhesive surface, electronic components provided on an upper surface of the base, the electronic components comprising a power source, a processor, memory in association with the processor, a digital to analog converter, an analog to digital converter, transducers, a pulse detection signal, and a switch to activate the electronic components,

removing the peel-away layer and exposing the lower adhesive surface and adhering the patch to the patient's skin over the artery,

operating the switch to activate the electronic components, wherein the processor generates an ultrasound wave digital signal and transmits the ultrasound wave digital signal to the digital to analog converter, the digital to analog converter converts the ultrasound wave digital signal to a converted ultrasound wave, the digital to analog converter transmits the converted ultrasound wave to at least one of the transducers, in response to receiving the converted ultrasound wave the at least one of the transducers emits a transmitted ultrasound wave toward the patient's artery, the transducers receive reflected ultrasound waves, the transducers transmit the reflected ultrasound waves to the analog to digital converter, the analog to digital converter converts the reflected ultrasound waves to reflected ultrasound wave digital signals and transmits the reflected ultrasound wave digital signals to the processor, the processor receives the reflected ultrasound wave digital signals and analyzes the ultrasound wave digital signal and the reflected ultrasound wave digital signal to determine whether a blood pulse is detected in the patient's artery, the processor causes the pulse detection signal to emit a pulse signal corresponding to a strength and a frequency of the blood pulse when blood pulse is detected and the processor causes the pulse detection signal to emit a no-pulse signal when blood pulse is not detected,

observing the pulse detection signal,

initiating cardiac resuscitation treatment when the no-pulse signal is observed, and

determining whether cardiac resuscitation treatment is needed when the pulse detection signal emits a pulse signal corresponding to a weak blood pulse.

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