US 20190388056A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2019/0388056 A1**

Rodriquez (43) **Pub. Date: Dec. 26, 2019**

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

(71) Applicant: **Gerardo Rodriquez**, Apo, AE (US)

(72) Inventor: **Gerardo Rodriquez**, Apo, AE (US)

(21) Appl. No.: **16/508,885**

(22) Filed: **Jul. 11, 2019**

Related U.S. Application Data

(63) Continuation-in-part of application No. 15/834,044, filed on Dec. 6, 2017.

(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.**

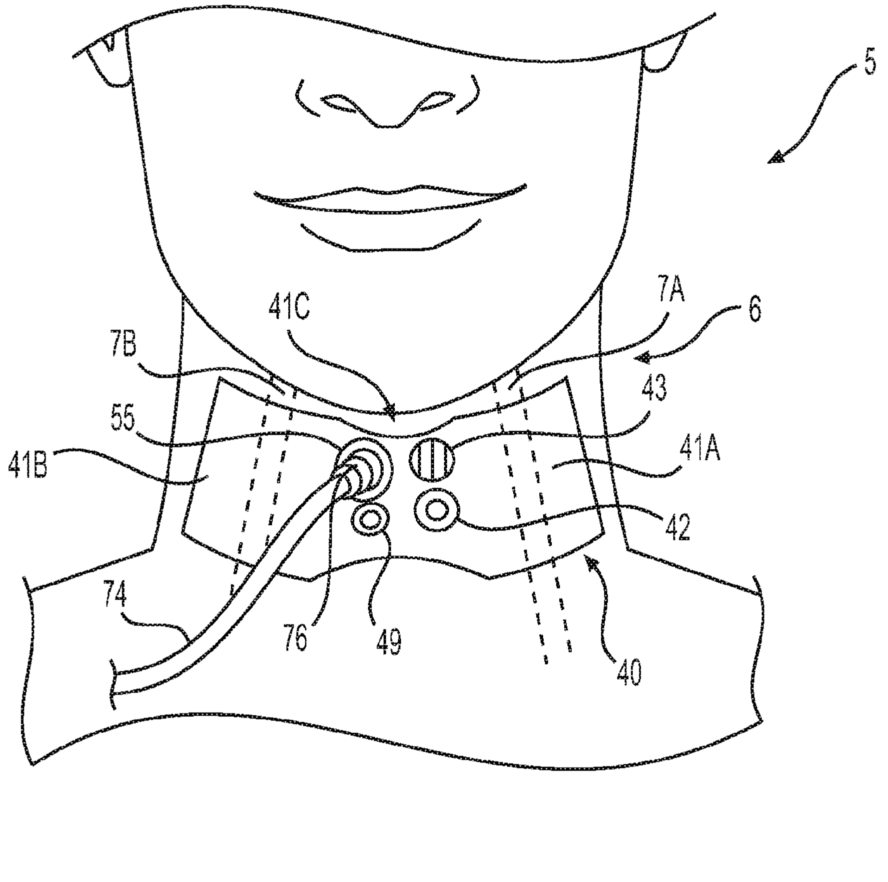
A61B 8/00	(2006.01)
A61B 5/00	(2006.01)
A61B 8/02	(2006.01)
A61B 8/06	(2006.01)
A61B 8/08	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 8/4236*** (2013.01); ***A61B 5/742*** (2013.01); ***A61B 8/02*** (2013.01); ***A61B 8/065*** (2013.01); *A61B 8/4281* (2013.01); *A61B 5/6833* (2013.01); *A61B 8/56* (2013.01); *A61B 8/0866* (2013.01); ***A61B 8/488*** (2013.01)

(57) **ABSTRACT**

A stand-alone continuous cardiac Doppler or acoustic pulse monitoring patch provides visual and auditory signals that a pulse or heartbeat 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. For the Doppler monitor, the patch includes a pad formed of a conductive medium to enhance transmission and reception of ultrasonic waves. For the acoustic monitor, the pad has a sound focusing portion that permits entry of sounds and focuses the sounds toward a microphone, and the pad also has a sound insulating portion surround the sound focusing portion. The patch includes an integral power source. The Doppler patch has transmitters and receivers to send and detect reflected ultrasonic waves and a transducer to convert the reflected waves into an electrical signal. The acoustic patch has a microphone to detect the sound of a heartbeat and a transducer to convert the sound energy into an electrical signal. A processor analyzes the Doppler wave signals or the acoustic signals. A light indicates the presence and strength of a pulse detected from the Doppler wave signals or a heartbeat detected by the microphone. A speaker and a vibrator may also to indicate the presence and strength of a pulse or a heartbeat. 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 or heartbeat is analyzed by the processor to determine the frequency and strength of blood flow or beating of the heart. The processor causes the light, speaker or vibrator to blink, beep or vibrate at a rate to indicate the frequency of rhythmic blood flow or heartbeat.



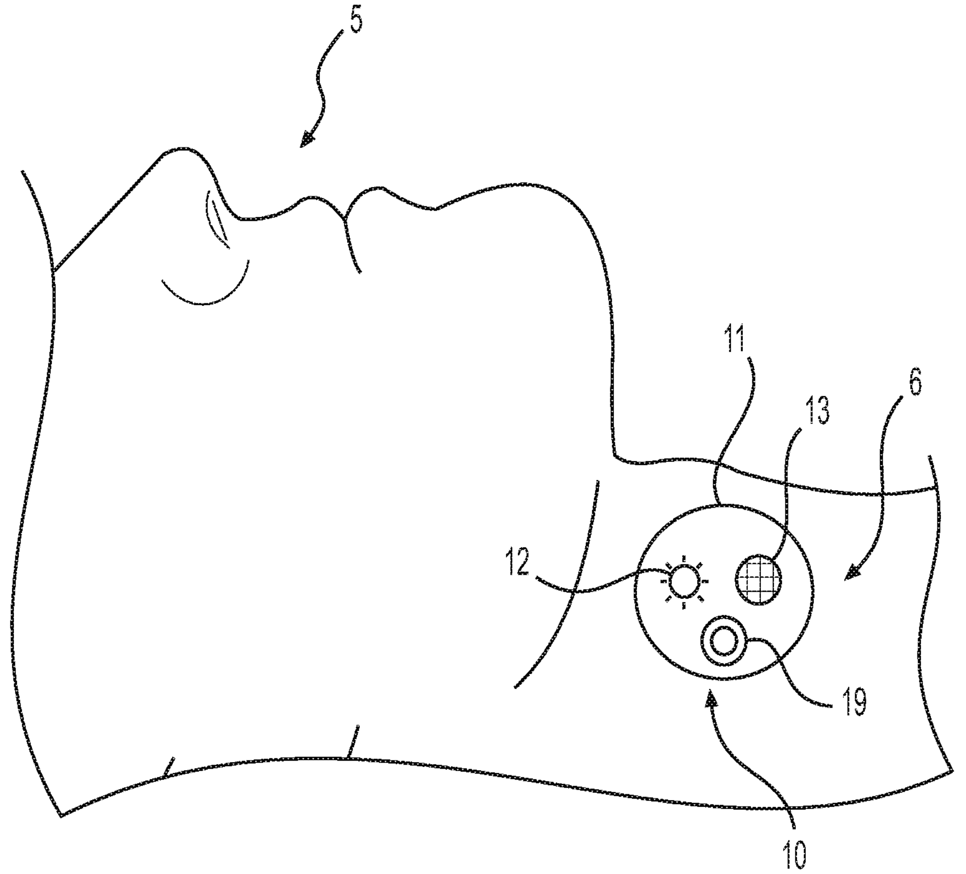


FIG. 1

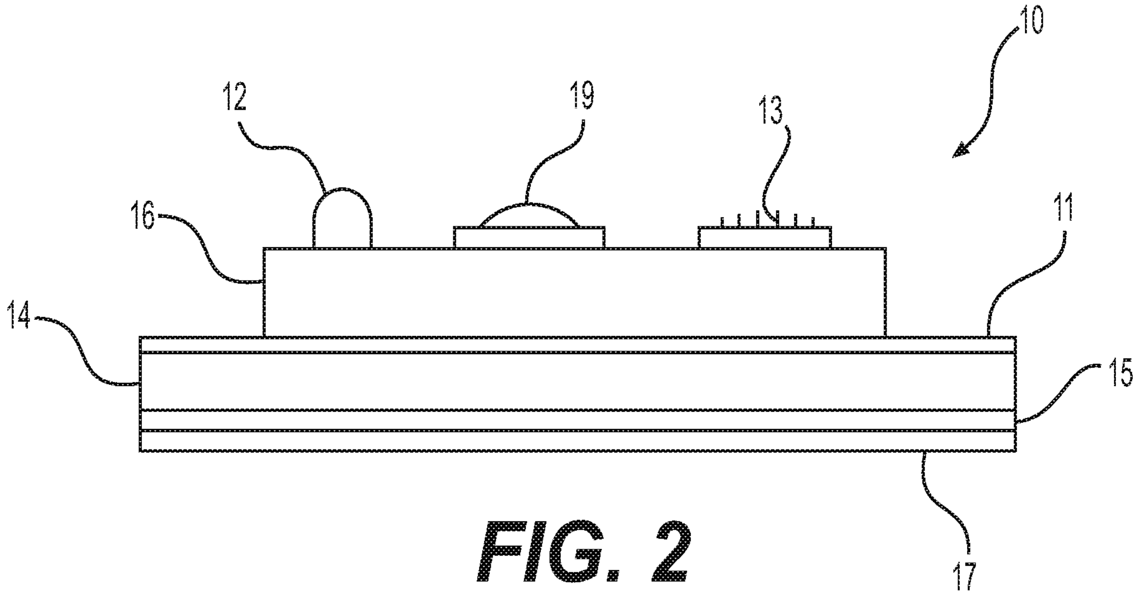


FIG. 2

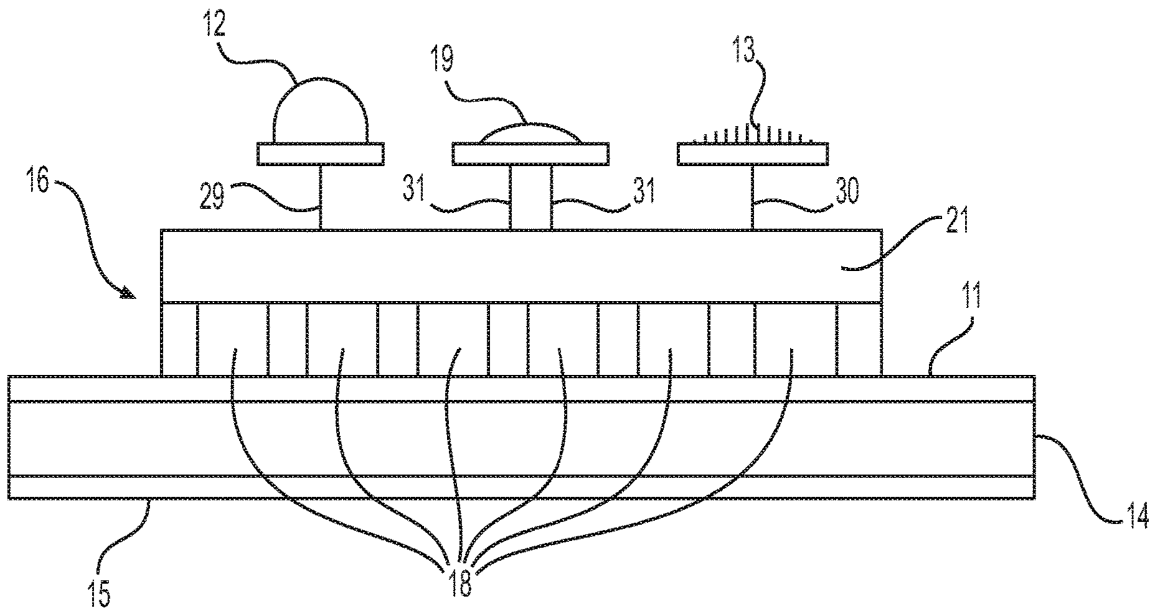

12
19
13
16
29
31
31
30
21
11
14
15
18

FIG. 3

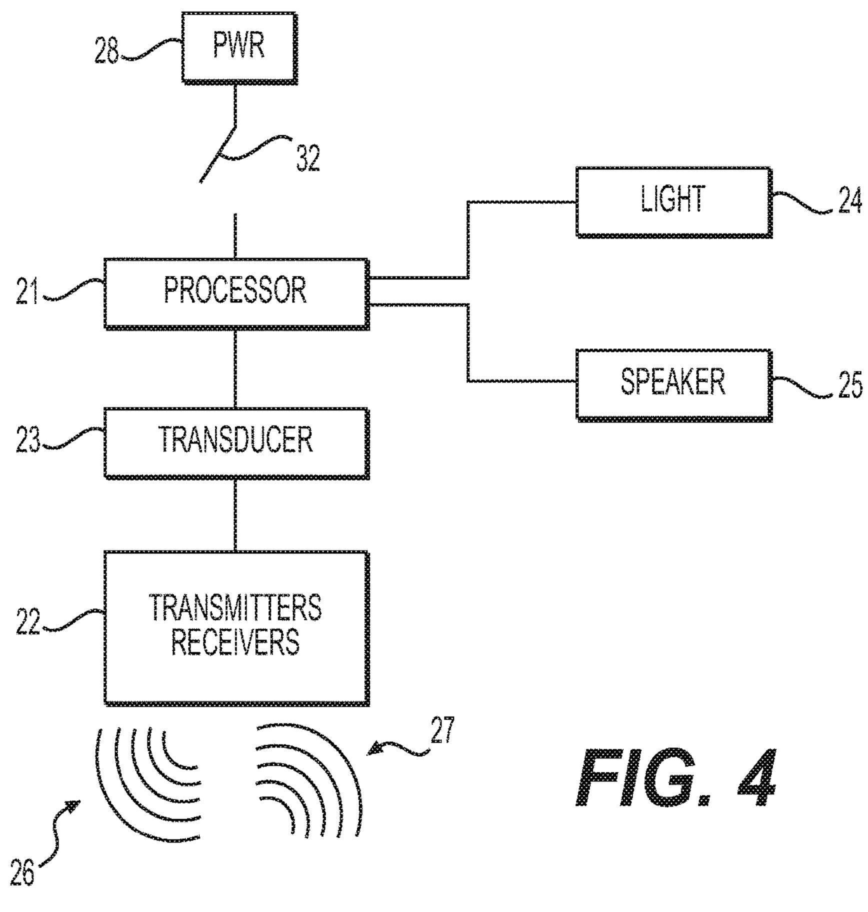

28
PWR
32
LIGHT
24
21
PROCESSOR
SPEAKER
25
23
TRANSDUCER
22
TRANSMITTERS
RECEIVERS
27
26

FIG. 4

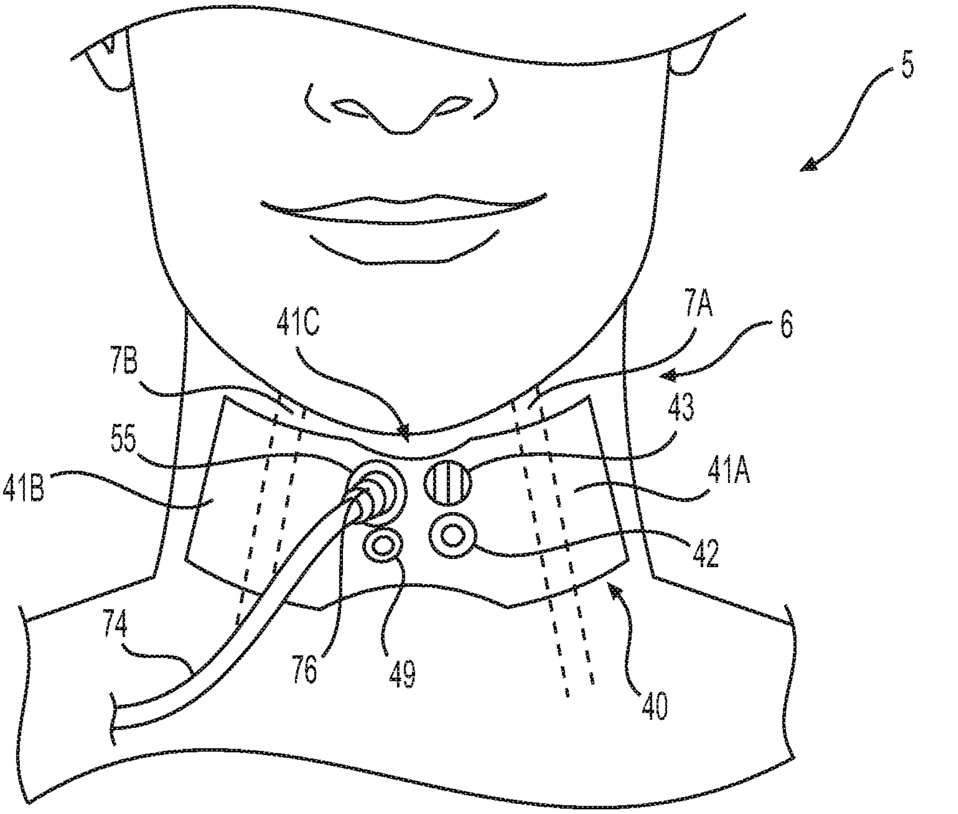


FIG. 5

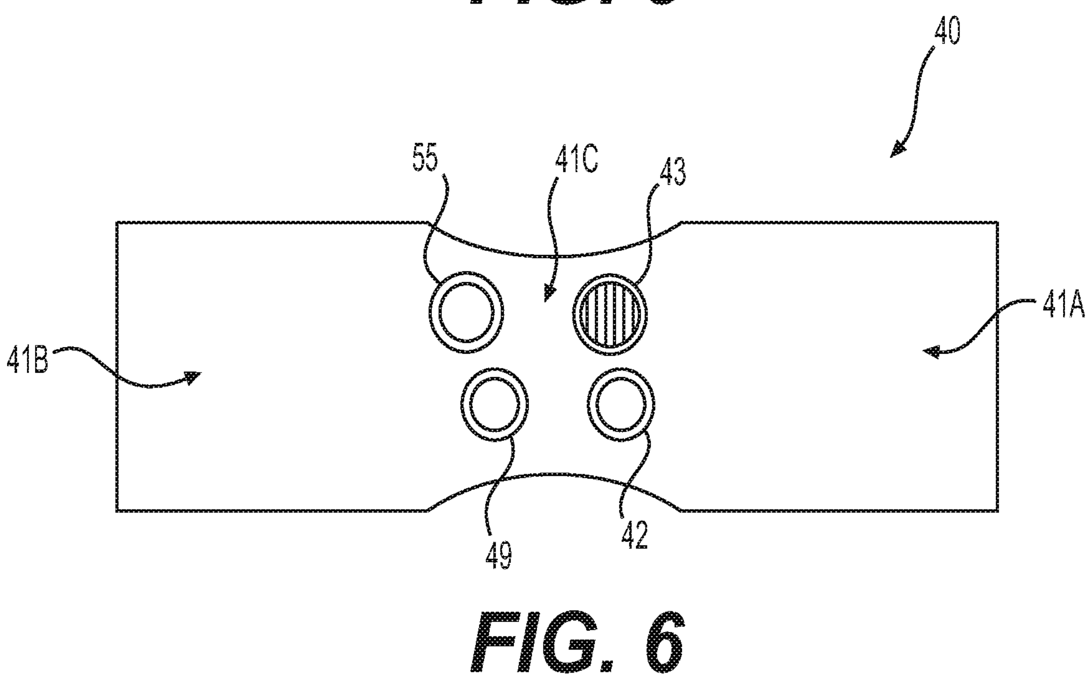


FIG. 6

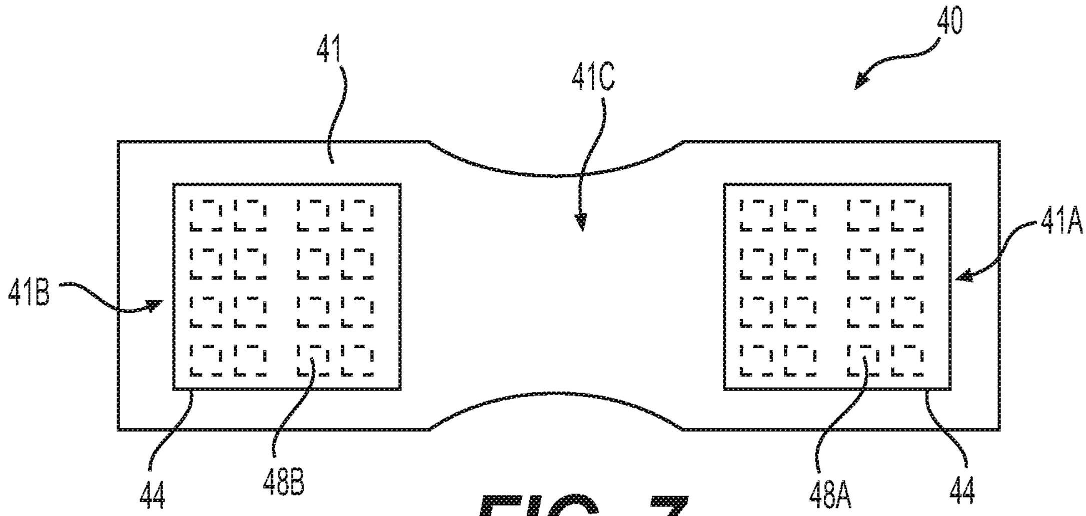

40
41
41C
41A
41B
44
48B
48A
44

FIG. 7

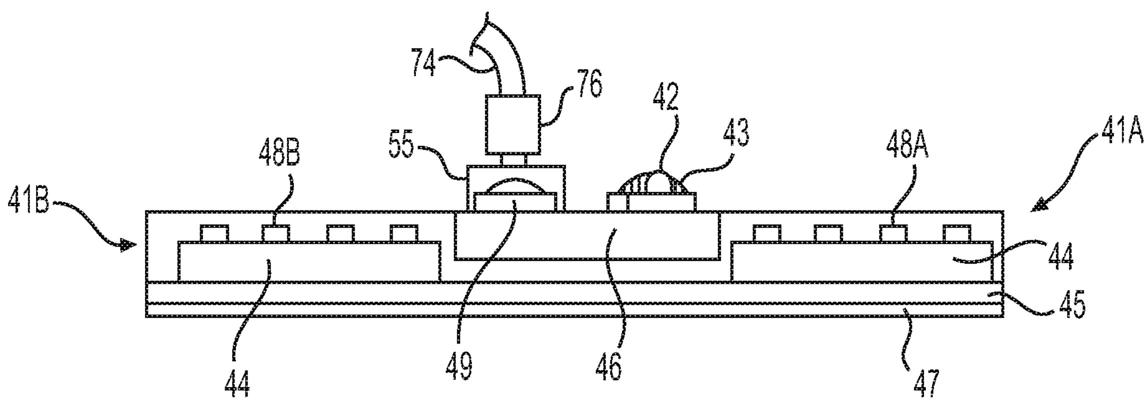
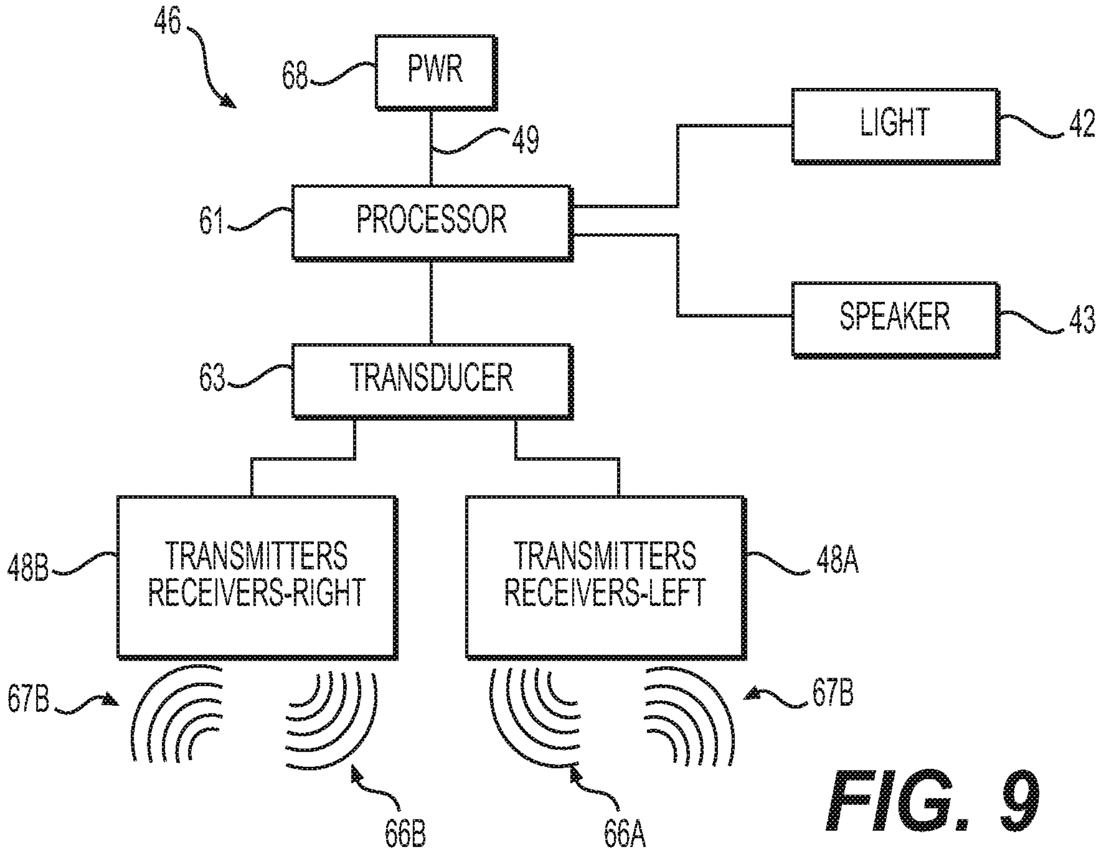
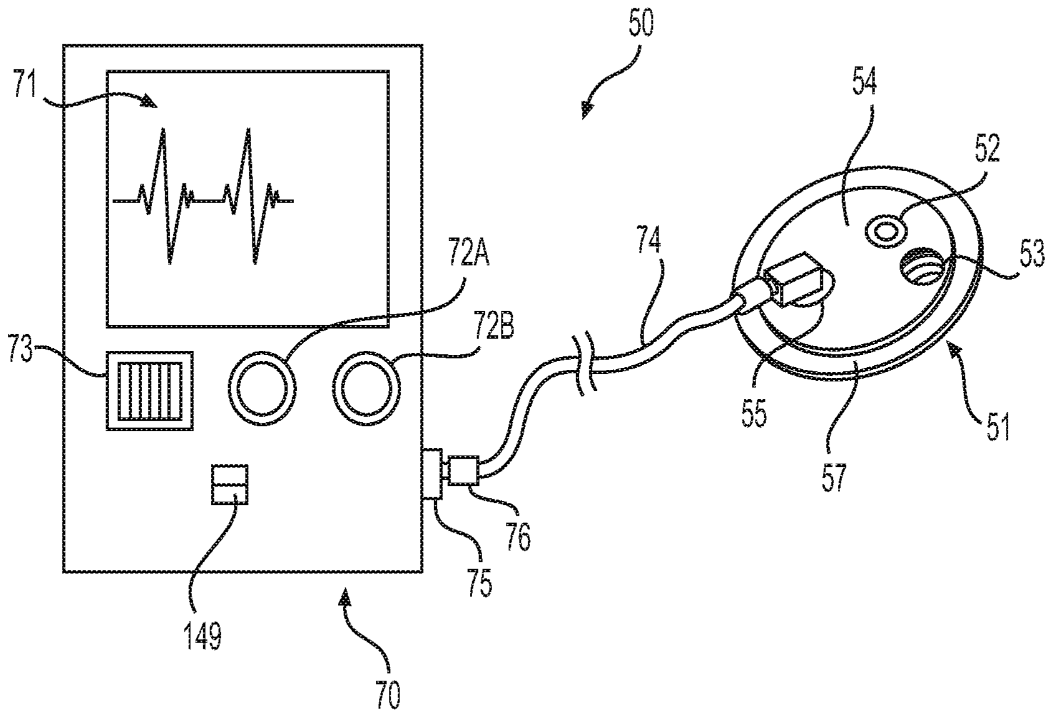

74
76
42
43
55
48B
48A
41A
41B
44
45
44
49
46
47

FIG. 8



46
68
PWR
49
LIGHT
42
61
PROCESSOR
SPEAKER
43
63
TRANSDUCER
48B
TRANSMITTERS RECEIVERS-RIGHT
TRANSMITTERS RECEIVERS-LEFT
48A
67B
67B
66B
66A

FIG. 9



50
71
54
52
72A
74
53
72B
73
55
51
57
76
75
149
70

FIG. 10

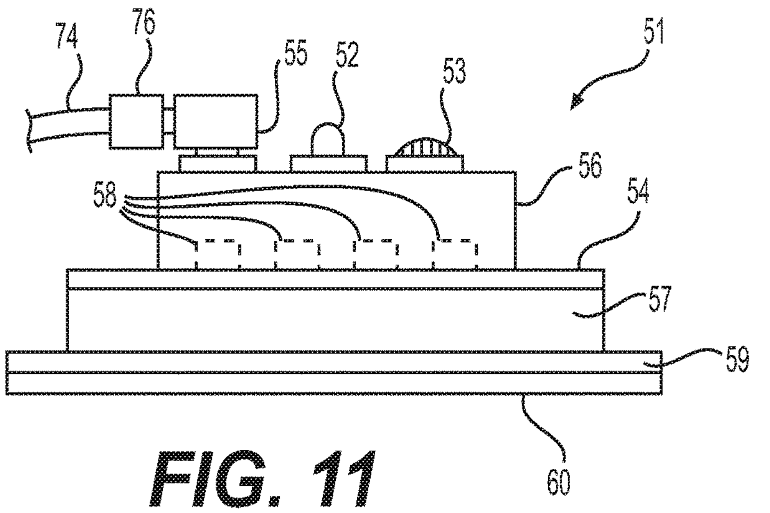

74
76
55
52
53
51
56
58
54
57
59
60

FIG. 11

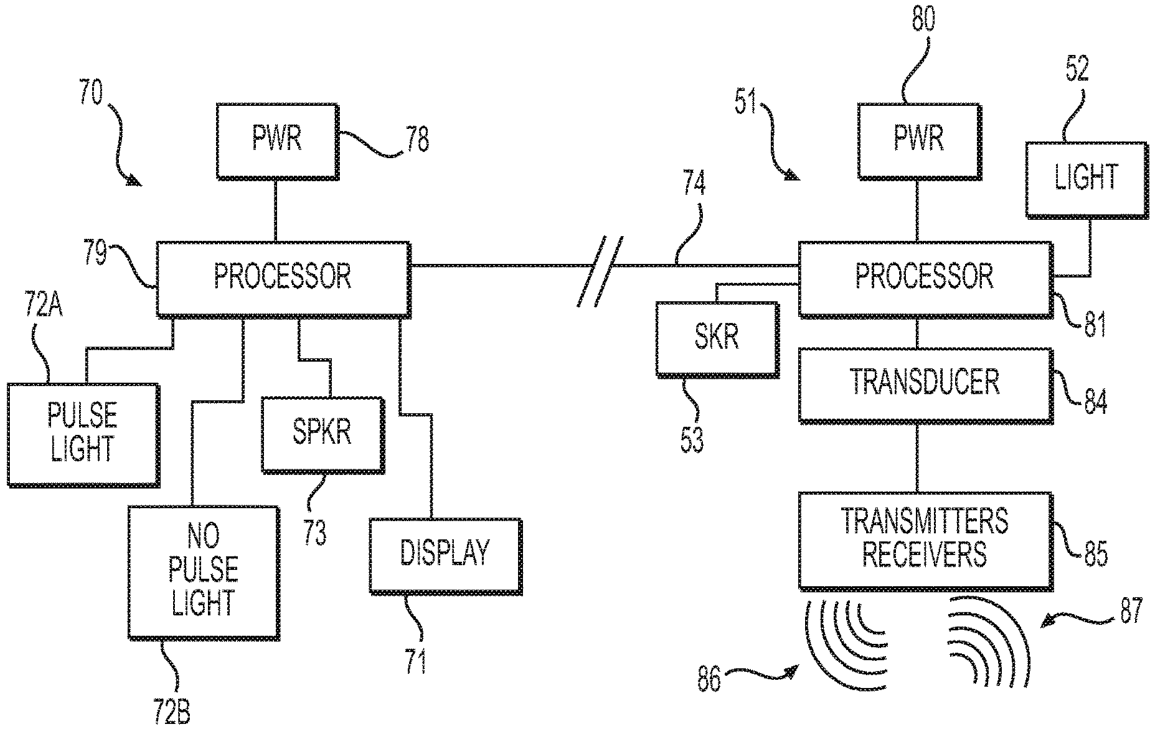

70
PWR
78
79
PROCESSOR
72A
PULSE LIGHT
NO PULSE LIGHT
72B
SPKR
73
DISPLAY
71
74
51
80
PWR
52
LIGHT
PROCESSOR
81
SKR
53
TRANSDUCER
84
TRANSMITTERS RECEIVERS
85
86
87

FIG. 12

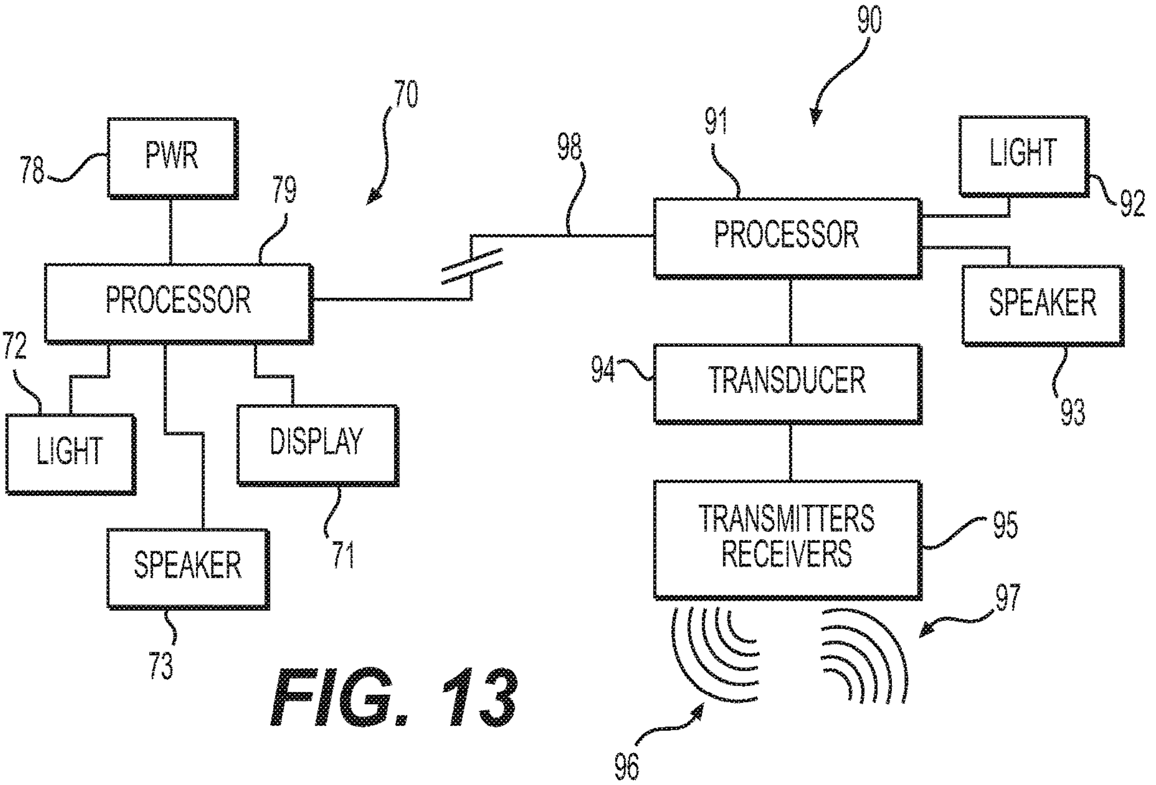

70
78
PWR
79
PROCESSOR
72
LIGHT
DISPLAY
71
SPEAKER
73
98
90
91
PROCESSOR
LIGHT
92
SPEAKER
93
94
TRANSDUCER
TRANSMITTERS
RECEIVERS
95
97
96

FIG. 13

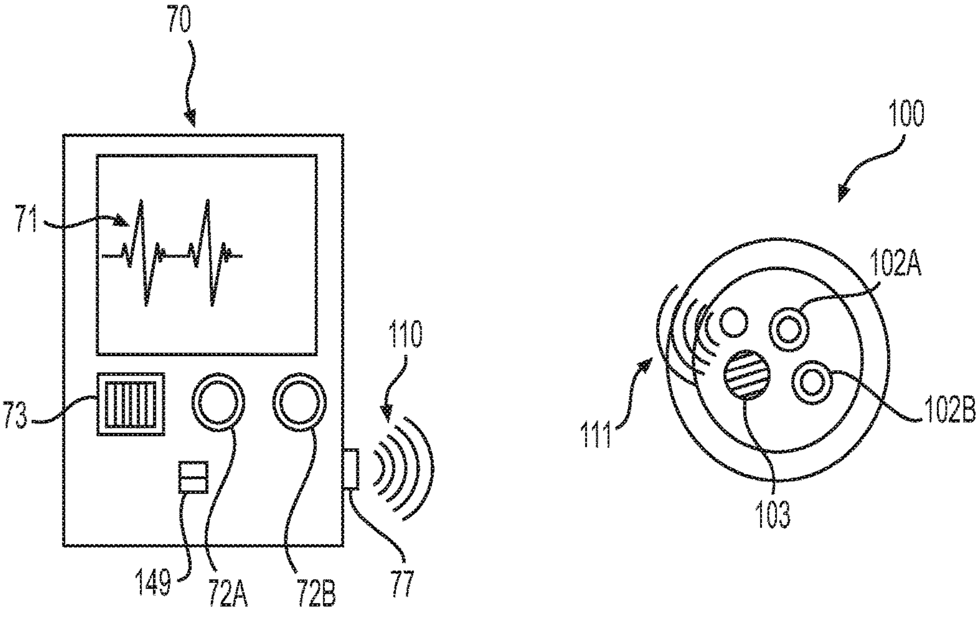

70
71
110
73
149
72A
72B
77
100
102A
102B
111
103

FIG. 14

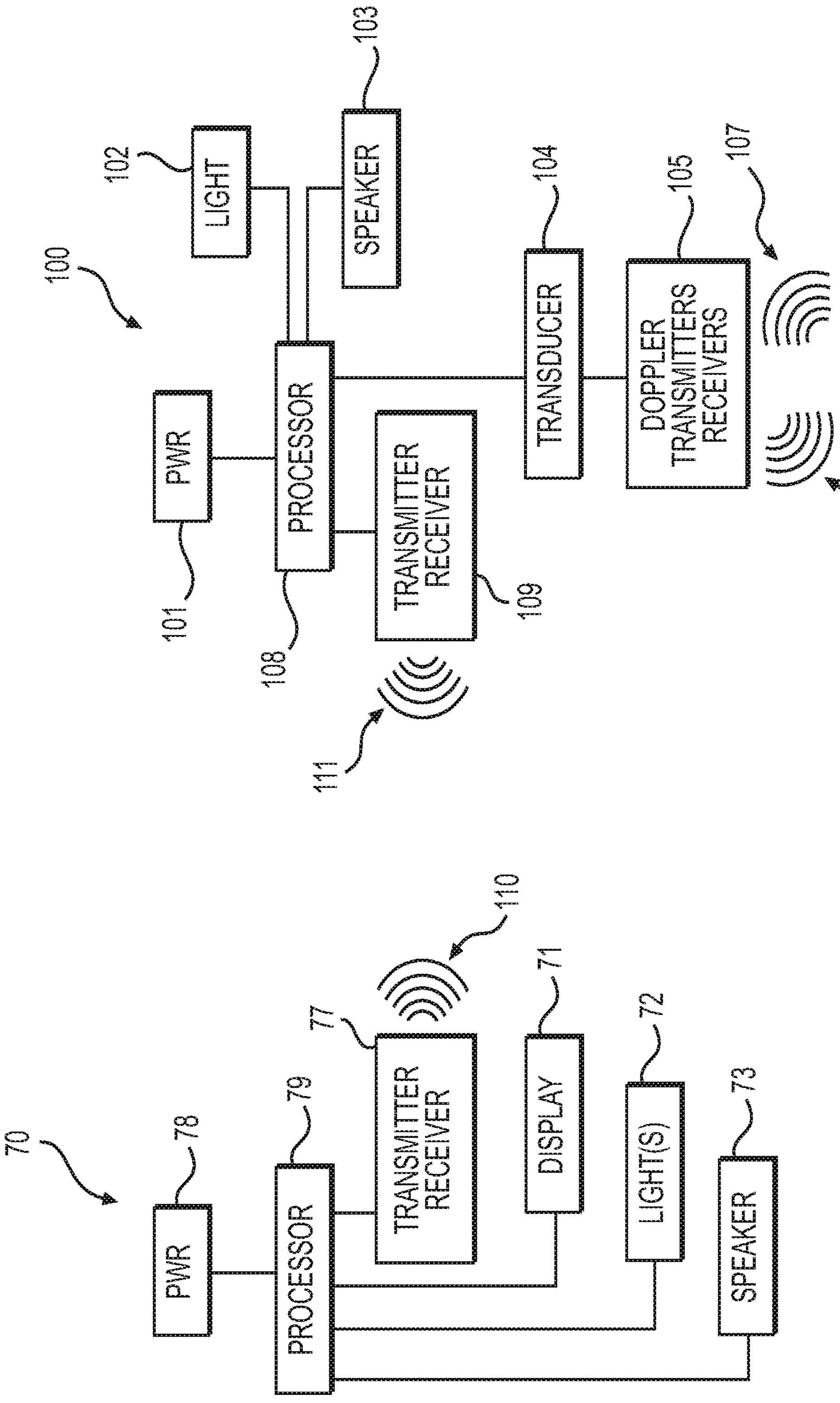
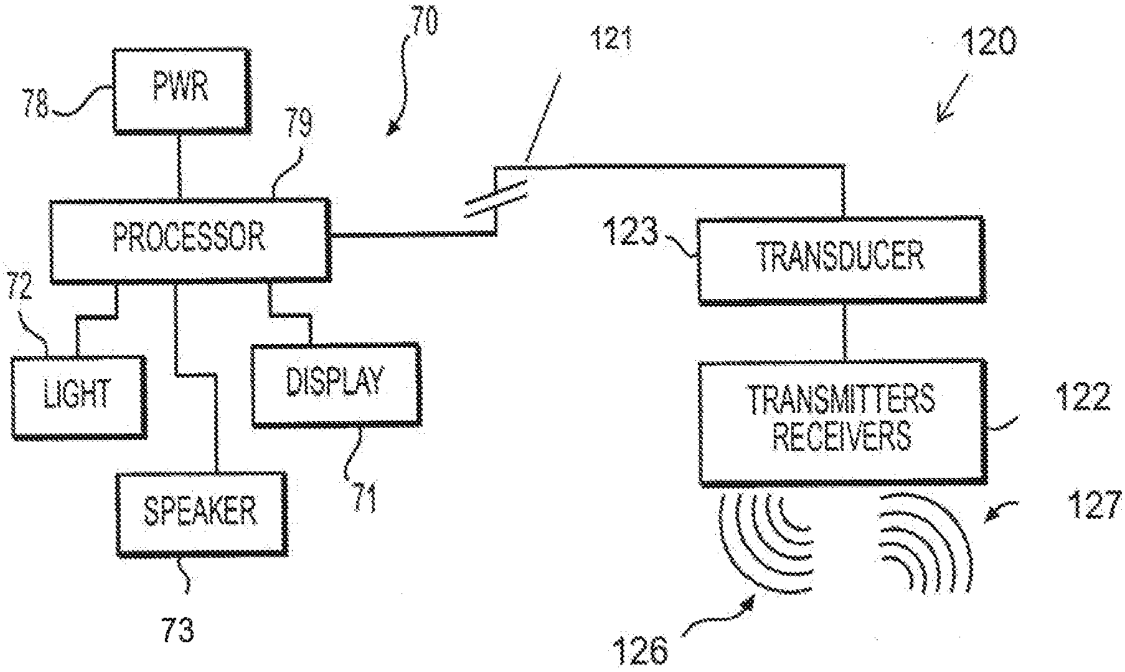

100
PWR
101
PROCESSOR
108
LIGHT
102
SPEAKER
103
TRANSMITTER RECEIVER
109
111
TRANSDUCER
104
DOPPLER TRANSMITTERS RECEIVERS
105
106
107
70
PWR
78
PROCESSOR
79
TRANSMITTER RECEIVER
77
110
DISPLAY
71
LIGHT(S)
72
SPEAKER
73

FIG. 15



70
121
120
PWR
78
79
PROCESSOR
123
TRANSDUCER
72
LIGHT
DISPLAY
TRANSMITTERS
RECEIVERS
122
SPEAKER
71
127
73
126

FIG. 16

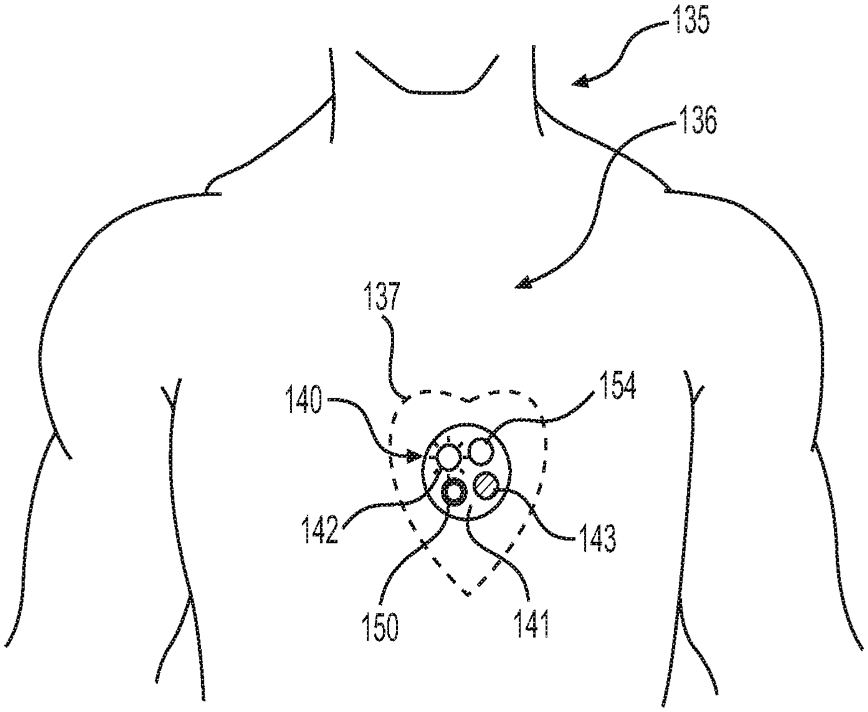

135
136
137
140
154
142
143
150
141

FIG. 17

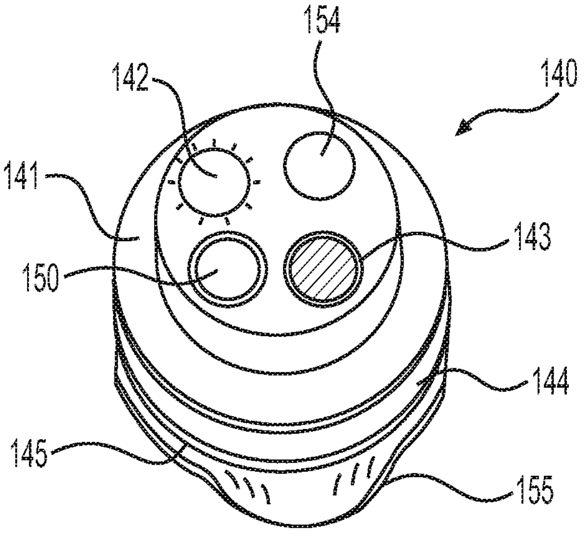
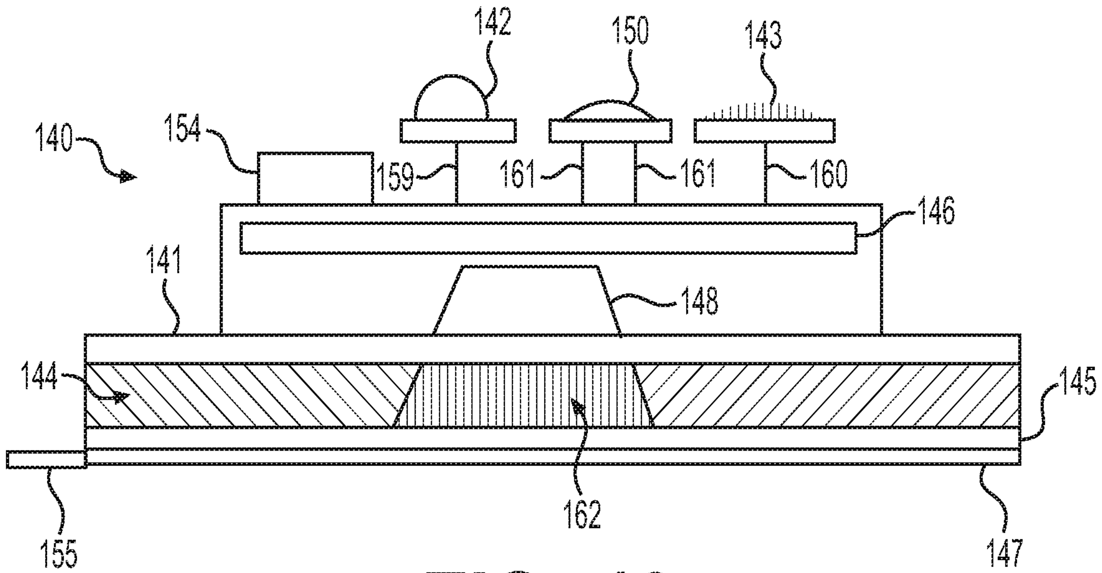
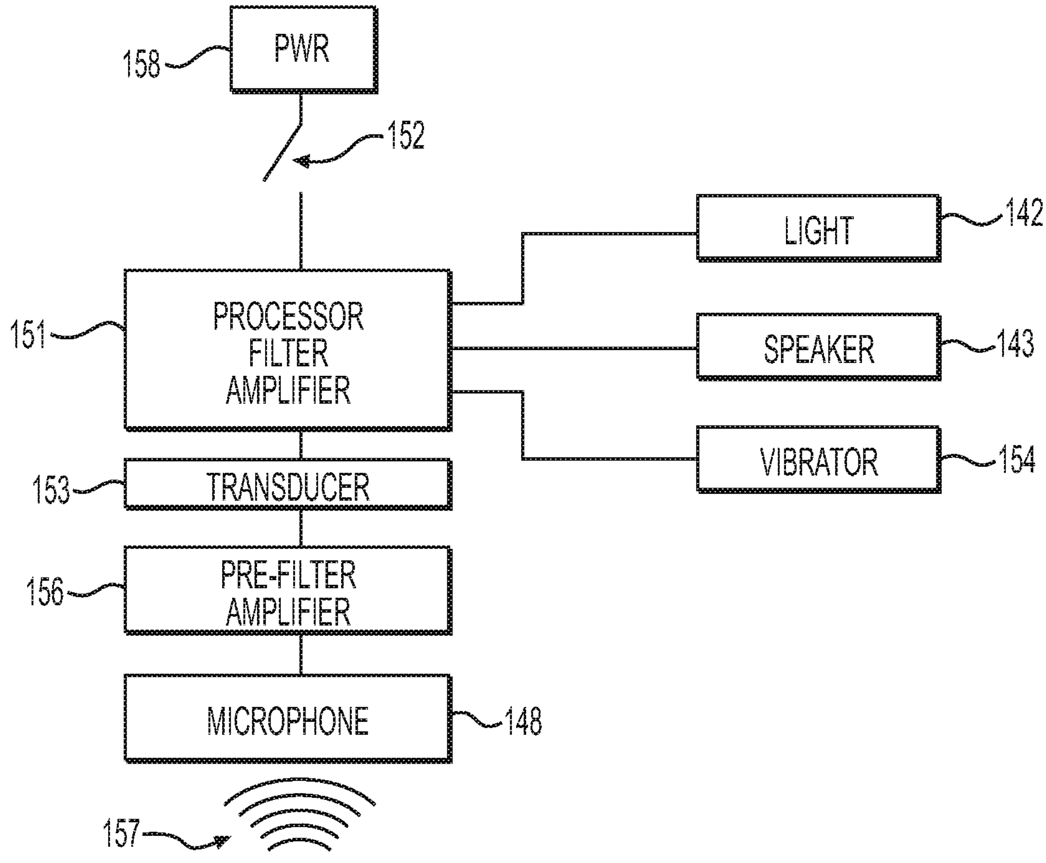

154
142
140
141
143
150
144
145
155

FIG. 18



142
150
143
140
154
159
161
161
160
146
141
148
144
145
162
155
147

FIG. 19



158
PWR
152
LIGHT
142
151
PROCESSOR
FILTER
AMPLIFIER
SPEAKER
143
VIBRATOR
154
153
TRANSDUCER
156
PRE-FILTER
AMPLIFIER
MICROPHONE
148
157

FIG. 20

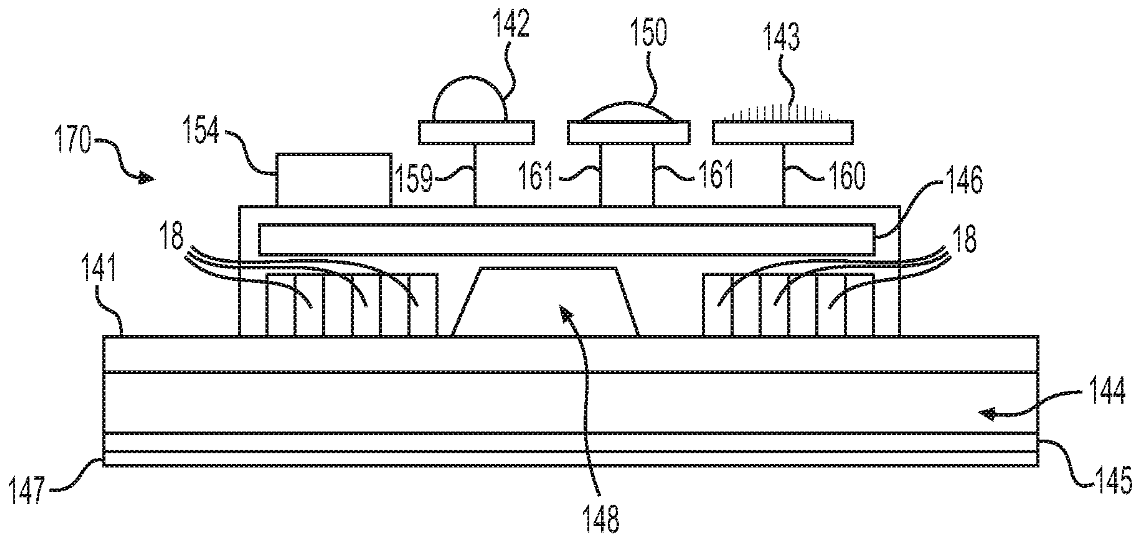

142
150
143
170
154
159
161
161
160
146
18
18
141
144
147
145
148

FIG. 21

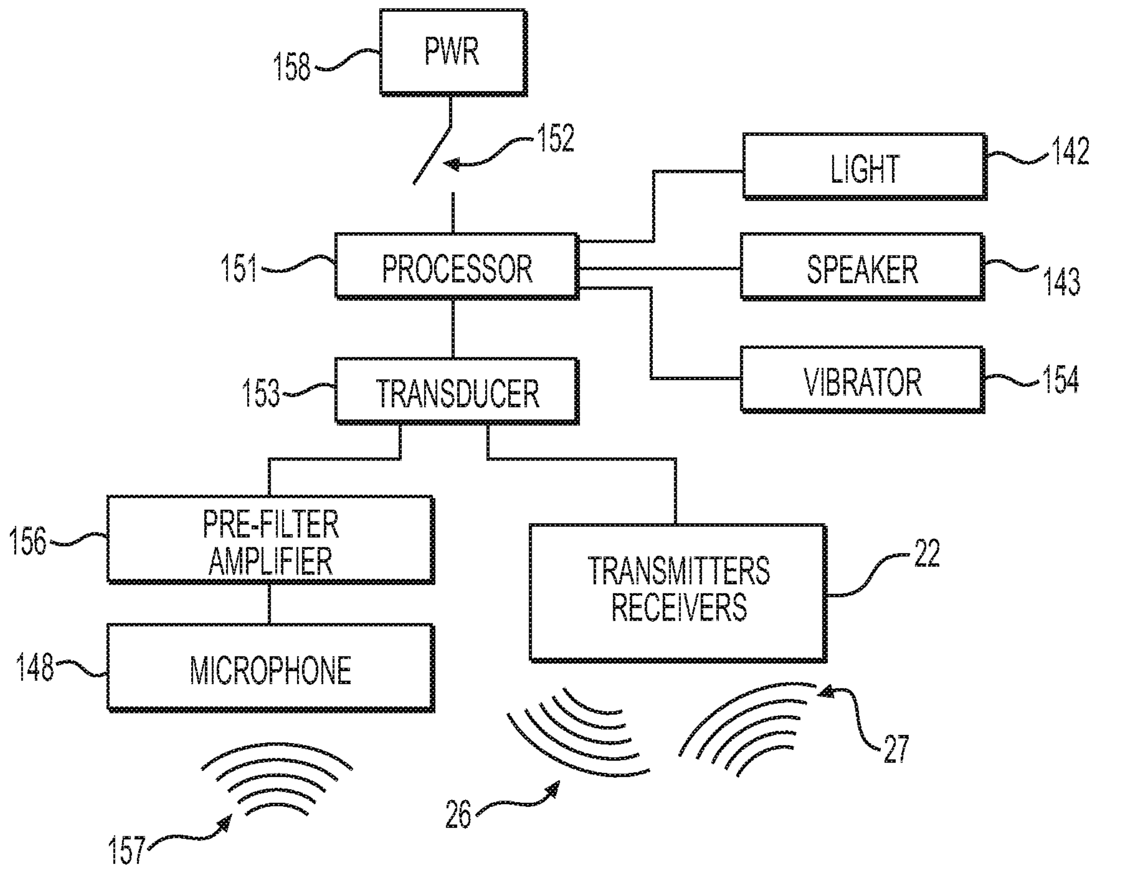

PWR
158
152
LIGHT
142
151
PROCESSOR
SPEAKER
143
VIBRATOR
154
153
TRANSDUCER
156
PRE-FILTER
AMPLIFIER
TRANSMITTERS
RECEIVERS
22
148
MICROPHONE
27
26
157

FIG. 22

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

CLAIM OF PRIORITY TO NON-PROVISIONAL AND PROVISIONAL APPLICATIONS (35 U.S.C. §§ 120 AND 119(E))

[0001] Pursuant to 35 U.S.C. § 120 and 37 CFR 1.78(d)(2), this application is a continuation-in-part of prior non-provisional patent application Ser. No. 15/834,044 filed on Dec. 6, 2017 ("the '044 Non-Provisional application"). The '044 Non-Provisional application claimed 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. Accordingly, this continuation-in-part application is entitled to the benefit of these provisional applications. The Ser. No. 15/834,044 non-provisional application and the 62/430,872 and 62/523,765 provisional applications are incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention relates to a stand-alone continuous cardiac Doppler and acoustic pulse monitoring patch that provides visual and auditory signals that blood flow is detected in a subject. More specifically, the Doppler pulse monitoring patch of 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. Similarly, the Acoustic pulse monitoring patch of the present invention is a small patch that is applied to the skin of a subject, preferably over the heart, 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/AHAECC/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] Similarly, recent developments in electronic stethoscopes have made available stethoscopes with electronic acoustic sensors to detect the sound of a beating heart and analyze the sound with a processor which in turn displays the heartbeat waveform on a screen. As with the Doppler monitors, these acoustic stethoscopes must be held in place and a separate display must be observed to see the heartbeat waveform, making it awkward to administer CPR while continuing to monitor real-time information. These electronic stethoscopes can also monitor a subject's breathing, which can identify shallow breathing, seen in overdose states such as alcohol poisoning or opiate overdose, and apnea, the absence of breathing. With the rapid increase in opiate-related overdoses and deaths, there is a need for a monitor that is easily and quickly applied to provide constant, real-time detection of a subject's breathing without reliance on external devices.

[0008] Even in the hospital setting existing devices pose problems. For example, when a subject requires an X-ray or other scan, existing ECG, Doppler, and acoustic 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.

[0009] Identifying and tracking the mechanical blood flow of the heart and large arterial vessels in real time is underutilized and important. The current system of isolated finger pulse or Doppler pulse checks is challenging, even for medical professionals.

[0010] Needed is a pulse monitor that is easily and quickly applied to provide constant, real-time detection of a subject's blood flow without reliance on external devices.

SUMMARY OF THE INVENTION

[0011] The present invention discloses a stand-alone continuous cardiac Doppler and acoustic 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. The Doppler monitor should be applied near a large artery and the acoustic monitor should be applied over the heart. The adhesive surface of the patch secures the monitor to the skin of the patient and also includes a layer of material, such as gel, to provide a conductive medium for the Doppler monitor, to enhance transmission and reception of ultrasonic waves, or sound isolation for the acoustic monitor, to enhance reception of heartbeats and insulate against or absorb unwanted sounds. The patch includes a power source, electronics associated with the Doppler or acoustic signals, a processor to control and analyze the signals, a memory, and one or more of a light, speaker, or vibration generator to indicate the presence and strength of a pulse.

[0012] The electronics of the Doppler patch include 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, and a memory to store a subject's pulse signals as well as models of signal patterns to which the subject's measured signals may be compared. 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. In addition, a vibrator can be added to indicate the frequency and strength of blood flow by touching to patch. The absence of blood flow may be indicated by the absence of light or sound or vibration, or by separate or different light or auditory or vibratory signals intended to convey the absence of blood flow and potential emergency.

[0013] 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.

[0014] The electronics of the acoustic patch include a microphone to detect sound waves, a transducer to convert the received sound waves to electrical signals, a processor to analyze the signals, and a memory to store a subject's heartbeat signals as well as models of signal patterns to which the subject's measured signals may be compared. The presence of a heartbeat is analyzed by the processor to determine its frequency and strength. The processor causes a light to blink at a rate to indicate the frequency of the heartbeat. 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 heartbeat. The processor may also drive a speaker to emit sounds, such as beeps, that indicate the frequency and strength of the heartbeat. In addition, a vibrator can be added to indicate the frequency and strength of the heartbeat by touching to patch. A weak or failing heartbeat, or the absence of a heartbeat, may be indicated by the absence of light or sound or vibration, or by separate or different light or auditory or vibratory signals intended to convey the absence of a heartbeat and potential emergency. In a further embodiment, the acoustic monitor also listens for a subject's breathing and the processor analyzes detected sounds to identify known breathing patterns associated with symptoms of distress, such as shallow breathing, which is an indicator of an overdose state from opiates or alcohol poisoning, or apnea. As with recognized indicators of cardiac distress, the processor can drive the light, speaker or vibrator to indicate the frequency and strength of the subject's breathing.

[0015] In an alternative embodiment, an integrated continuous cardiac Doppler or acoustic 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 or vibratory 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 or acoustic signal data wirelessly to the display unit, which will process and display the data.

[0016] 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

[0017] 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.

[0018] FIG. **2** is a side view showing the layers the stand-alone pulse-monitoring patch.

[0019] FIG. **3** is a side, cut-away view showing the arrangement of components of the stand-alone pulse-monitoring patch invention.

[0020] FIG. **4** is a block diagram of the electronic circuitry of the stand-alone pulse-monitoring patch invention.

[0021] FIG. **5** shows a butterfly patch embodiment of the stand-alone pulse-monitoring patch invention applied to the neck of a patient.

[0022] FIG. **6** is a top view of the stand-alone pulse-monitoring butterfly patch invention.

[0023] FIG. **7** is a bottom view of the stand-alone pulse-monitoring butterfly patch invention.

[0024] FIG. **8** is a side, cut-away view showing the arrangement of components of the stand-alone pulse-monitoring butterfly patch invention.

[0025] FIG. **9** is a block diagram of the electronic components of the stand-alone pulse-monitoring butterfly patch invention.

[0026] FIG. **10** is a schematic of a stand-alone pulse-monitoring patch connected by a conductive cable to a display unit.

[0027] FIG. **11** is a side, cut-away view of a stand-alone pulse-monitoring patch with a connector port for the conductive cable connection.

[0028] 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.

[0029] 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.

[0030] FIG. **14** is a schematic of a simplified pulse-monitoring patch connected wirelessly to a display unit.

[0031] FIG. **15** is a block diagram of the components of an alternate embodiment of a patch and a display unit connected wirelessly.

[0032] FIG. **16** is a block diagram of the components of an alternate embodiment of a simplified patch and a display unit system.

[0033] FIG. **17** shows a stand-alone continuous cardiac acoustic pulse-monitoring patch with visual and auditory alerts of the present invention applied to the chest of a patient.

[0034] FIG. **18** is a side view showing the layers the stand-alone acoustic pulse-monitoring patch.

[0035] FIG. **19** is a side, cut-away view showing the arrangement of components of the stand-alone acoustic pulse-monitoring patch invention.

[0036] FIG. **20** is a block diagram of the electronic circuitry of the stand-alone acoustic pulse-monitoring patch invention.

[0037] FIG. **21** is a side, cut-away view showing the arrangement of components of the stand-alone combined Doppler and acoustic pulse-monitoring patch invention.

[0038] FIG. **22** is a block diagram of the electronic circuitry of the stand-alone combined Doppler and acoustic pulse-monitoring patch invention.

DETAILED DESCRIPTION

[0039] 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 **7**B 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**.

[0040] 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**.

[0041] 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 stand-alone 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.

[0042] 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.

[0043] 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.

[0044] 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.

[0045] 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** (**7**A 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.

[0046] 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.

[0047] 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 mange 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).

[0048] 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.

[0049] The invention also provides a simple continuous cardiac Doppler monitor patch **10** for checking fetal distress in pregnancy.

[0050] 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, **41**A and **41**B, covers that part of the throat over the left **7**A and right **7**B carotid arteries. In this position, the monitor **40** detects a pulse from either the left **7**A or right **7**B 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, **41**A at the left and **41**B at the right, of the butterfly patch **40** includes an array of transmitters/receivers, **48**A and **48**B, respectively. As described above, the transmitters of each array, **48**A and **48**B, emit ultrasonic waves, **66**A at the left and **66**B at the right, and the receivers, **67**A at the left and **67**B at the right, detect reflected waves. The reflected wave signals, **67**A and **67**B, 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, **67**A and **67**B, 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.

[0051] The butterfly patch **40** is placed over the front of the subject's **5** neck **6** so that the left wing **41**A is over the left carotid artery **7**A and the right wing **41**B is over the right carotid artery **7**B. 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, **48**A and **48**B, will begin transmitting ultrasonic signals, **66**A and **66**B, and receiving their reflections, **67**A and **67**B. 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**.

[0052] 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 **41**C 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.

[0053] 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, **48**A and **48**B, 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 **72**A, 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.

[0054] 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, **48**A and **48**B, arrayed in or over the base **41**. The transmitters emit ultrasonic waves, **66**A and **66**B, and the receivers detect reflected waves, **67**A and **67**B. The reflected wave signals, **67**A and **67**B, are demodulated and analyzed by a processor **61**, or the transmitted ultrasonic wave signals may be combined with the demodulated reflected wave signals, **67**A and **67**B, 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, **67**A and **67**B, 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.

[0055] 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 and 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 and analyzed to evaluate the heart's behavior from the time the monitor patch was applied.

[0056] 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 **41**C 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.

[0057] 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, **72**A and **72**B, so that the heart rhythm and flow strength can be indicated on one light or light cluster **72**A and an emergency light indicator **72**B 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.

[0058] 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.

[0059] 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 **72**A to display the pulse in the manner described above, A no-pulse light **72**B 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.

[0060] 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**.

[0061] Referring to FIGS. **14** and **15**, an alternative embodiment is disclosed whereby the stand-alone monitor patch **100** transmits and receives **111** 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**.

[0062] 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 discarded after use, while the display unit **70** may be re-used.

[0063] FIGS. **17** through **20** show the stand-alone continuous acoustic heart monitor patch **140**. FIG. **17** shows the acoustic monitor patch **140** applied to the chest **136** of a patient **135** over the patient's **135** heart **137**. In this position, the acoustic monitor **140** will be in the best position to detect the sound (**157** shown in FIG. **20**) of a beating heart **137**. The chest **136** over a subject's **135** heart **137** is best position from which to detect a heartbeat, since it is in the closest distance to the heart **137** and provides a direct path through which the sound **157** of the heartbeat may travel. The acoustic monitor **140** may be placed over arteries, such as the carotid, femoral or radial arteries, in order to listen for heartbeats **157** while CPR is being applied to the chest **136** or when other procedures require access to the chest **136**. The acoustic monitor **140** is secured on the subject's **135** chest **136** over the heart **137** by removing the peel-away layer **147** to expose the adhesive **145** (shown in FIG. **19**). A tab **155** extending out from the edge of the peel-away layer **147** can be gripped easily to facilitate removal. The on/off switch **150** is turned to the on position and the acoustic monitor's **140** microphone **148** (shown in FIG. **19**) will begin listening for a heartbeat. When blood is being pumped by the heart **137**, the heartbeat will be heard, along with other sounds, by the acoustic monitor's **140** microphone **148**. The sounds **157** are received by a microphone **148** and the energy of the sound is transmitted to a transducer **153**. The sound energy from the microphone **148** may be pre-filtered (**156** in FIG. **20**) to remove sounds are outside the desired range for detection. The sounds may also be amplified so that increase the acoustic signals to a range for which the full resolution of the acoustic monitor patch **140** is designed to analyze. The transducer **153** includes an analog-to-digital (A-to-D) converter that converts the analog acoustic signals into digital signals. The digital signals are sent to the digital signal processor (DSP) **153**. The processor **153** has integrated memory and software that allows digital filtering of the signals to eliminate as much unwanted noise as possible by identifying and removing digital signals outside the range targeted for detection. The processor **153** may use a field programmable gate array (FPGA) to detect targeted acoustic signal data in order to extract information about known sound patterns. The processor **153** compares the digital signal patterns with heartbeat models stored in the processor's **153** memory to distinguish the sounds associated with a heartbeat from other sounds. For example, the heartbeat signals **157** can be compared to known signal patterns of a normal heartbeat as well as patterns associated with known abnormal heartbeats (arrhythmia), such as premature atrial or ventricular contractions, atrial fibrillation or flutter, paroxysmal supraventricular or accessory pathway tachycardia, ventricular tachycardia or fibrillation, bradyarrhythmias, etc. The processor **153** determines the frequency and strength of the heartbeat and causes a light **142** on the upper surface of the acoustic monitor patch **140** to blink in time with the frequency of the heartbeat. The intensity of the light **142** may be varied to indicate the strength or weakness of the heartbeat. This rhythmic blinking of the light **142** may further be indicated by an audible sound, such as a beep, from a speaker **143**. Additionally, the monitor patch **140** may include a vibrator **154**, such as a pancake vibration motor, to provide a sensory indicator the rhythm and strength of the heartbeat. By placing a finger on the monitor patch **140**, the subject's **135** heartbeat can be felt through the vibrator **154** when surrounding conditions make seeing the light **142** or hearing the speaker **143** difficult, as in a fire, where smoky and noisy conditions may make other indicators difficult to detect.

[0064] FIG. **19** illustrates the parts of the acoustic monitor patch **140**. The bottom of the monitor patch **140** is formed by a base **141**, which supports the circuitry **146**. Under the base **141** is an acoustic pad **144** to focus the incoming sounds of a heartbeat **157** and insulate the microphone **148** from surrounding noise. The acoustic pad **144** may be a thermoplastic gel or a hydrogel, as discussed above. The density of the acoustic pad **144** may be varied to allow more sound to pass directly in front **162** of the microphone **148** while providing more sound insulation at the periphery. Beneath the conductive pad **144** is a thin adhesive layer **145** to fix the monitor patch **140** to the subject's skin. A peel-off layer **147** is disposed over the adhesive layer **145** to cover and preserve the adhesive until used. A tab **155** extending from the outer edge of the peel-away layer **147** and the base **141**, facilitates removing the adhesive layer **145**. Mounted on the base **141** is the circuitry **146**, described below. The circuitry **146** 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 **146** is a light **142** to indicate the strength and frequency of the detected heartbeat. The acoustic monitor patch **140** may also include a speaker **143**, vibrator **154**, and manual on/off switch **150**. A conductor **161** from the circuitry **146** to the light **142** allows electricity to flow to the light **142**. Similarly, a conductor **160** controls electrical flow to the speaker **143**, a conductor (not shown) controls electrical flow from the circuitry **146** to the vibrator **154**, and conductors **161** provide connectivity between the on/off switch **150** on the circuitry **146**.

[0065] FIG. **20** shows more detail of the circuitry **146**. A power source **158**, such as a small battery, provides integrated power to the electronic components of the stand-alone monitor patch **140**. A switch **152** controls power or can activate the circuitry **146** from a low-power consumption rest state. A microphone **148** receives the mechanical sound energy of a heartbeat **157**. A transducer **153** receives the electrical signals from the microphone **148**. In a preferred embodiment, the electrical signals from the microphone are prefiltered and amplified **156**. The transducer **153** converts the analog acoustic signals into digital signals and the digital signals are sent to the processor **153**. The processor **153** processes the digital signal to filter out unwanted noise, identify the presence or absence of sounds associated with a heartbeat **157**, and analyze the digital heartbeat data for frequency, strength, and arrhythmia patterns, as discussed above. Once the sound of a heartbeat is detected, the processor **151** causes the light **142** to blink in synchronization with the rhythm of the heartbeat. Similarly, the processor **151** may cause a speaker **143** to emit a sound, such as a beep, in synchronization with the rhythm of the heartbeat, and a vibrator **154** may vibrate in synchronization with the heartbeat to provide an indicator of the heartbeat that be detected by touch. The processor **151** will also analyze the acoustic signals **157** for known symptoms stored in the processor's **151** memory. Using the stored values, the processor **151** will cause the light **142** to blink with an intensity corresponding to the strength or weakness of the detected pulse. Similarly, based on the stored values, the processor **151** will cause the speaker **143** to beep with a volume corresponding to the strength or weakness of the detected pulse. Additionally, based on the stored values, the processor **151** will cause the vibrator **154** to vibrate with a rhythm and strength or weakness indicative of the detected heartbeat.

[0066] The light **142** may be an LED. In a preferred embodiment, the LED light **142** 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 **140**, the processor **151** will cause the light **142** to blink with a green color indicating a healthy pulse, but if a weak pulse is detected, the processor **151** will cause the light **142** to emit a yellow or red color. Alternatively, two or more lights **142** may be employed to indicate strength (i.e., more lights indicate a stronger heartbeat and fewer lights a weaker), or each LED is chosen to emit a different color. As described above, the processor **151**, 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 heartbeat. Similarly, the processor **151** will cause the speaker **143** to increase or decrease the volume, or change another characteristic of the emitted sound in relation to the strength or weakness of the detected heartbeat. Additionally, the vibrator **154** will cause the acoustic monitor patch **140** to vibrate with increasing or decreasing intensity in relation to the strength or weakness of the detected heartbeat. If the processor **151** detects a weak or declining pulse, the processor **151** will cause a color-changing LED light **142** 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 **151** may cause the speaker **143** to emit a different sound as a weak or declining pulse is detected. Additionally, the processor **151** may cause the vibrator **154** to vibrate more rapidly as a weak or declining pulse is detected. If a heartbeat is lost, the processor **151** can cause a color-changing LED light **142**, or a separate light, to emit a continuous bright, emergency red light. Similarly, if no heartbeat is detected or if a heartbeat signal fades completely, the processor **151** may cause the speaker **143** to emit a shrill continuous emergency sound.

[0067] In operation, the continuous cardiac acoustic monitor patch **140** will be applied to a patient **135** when a continuous pulse needs to be identified. The acoustic monitor patch **140** is activated or turned on by a switch **150**, the peel-off layer **147** is removed, exposing the adhesive **145**, and the monitor patch **140** is placed on a subject's **135** chest **136** over the heart **137**. It will be appreciated that the sequence of activating the switch **150** and removing the peel-off layer **147** may be reversed. In an alternative embodiment, the removal of the peel-off layer **147** will turn on or activate the circuitry **146** of the monitor patch **140**, either by turning a switch **150** to the active "on" position or by closing the on/off circuit **152** to the power source **158**. By deactivating the circuitry **146** of the monitor patch **140**, or cutting off power from the power source **158**, the switch **150** allows the monitor patch **140** to be inactive for long periods of time, such as during storage, yet be available in an instant when needed. When the monitor patch **140** is turned on, the processor **151** will direct the transducer **153** to send and receive acoustic signals **157** from the microphone **148**. The acoustic signals **157** are analyzed by the processor **151** and compared to values stored in the processor's **151** memory. If the heartbeat signals **157** correspond to a stored value for a heartbeat, the processor **151** will cause the light **142** to blink in synchronization with the heartbeat and with an intensity corresponding to the strength or weakness of the heartbeat. Similarly, the processor **151** will cause the speaker **143** to beep in synchronization with the heartbeat and with a volume corresponding to the strength or weakness of the heartbeat. Additionally, the processor **151** will cause the vibrator **154** to vibrate in synchronization with the heartbeat.

[0068] The acoustic monitor patch **140** may be used on unstable patients or patients with the potential of instability. Identifying the absence of a heartbeat is paramount to initiating CPR. The monitor patch **140** can also be applied while patients **135** are in motion. For example, moving patients **135** down stairs or transporting patients **135** in a helicopter. Moving patients **135** downstairs requires that the transporting personnel be at the head and foot of the stretcher, where they are unable to verify a continuous heartbeat. Similarly, air medical evacuations, and even automotive transportation, are loud and vibrations distracting, interfering with the detection of a heartbeat. For example, it is difficult to auscultate a heartbeat in a helicopter. The acoustic monitor patch **140** uses a light **142** as proof of a heartbeat. Moreover, in low visibility environments, the acoustic monitor patch **140** uses a speaker **143** as proof of a heartbeat. Additionally, in situations involving low visibility and loud ambient noise, where the light **142** and speaker **143** may be difficult to detect, such as in fires or battlefields, the vibrator **154** provides another means to detect the presence or absence of a heartbeat in a subject **135**.

[0069] The acoustic monitor patch **140** will, preferably, be placed on a subject's **135** chest **136** over the heart **137**. In situations where this is impeded, the acoustic monitor patch **140** may be placed over a large artery **6** (as in FIG. **1**), such as the carotid, radial, or femoral arteries.

[0070] The acoustic monitor patch **140** of the present invention is designed as a stand-alone that integrates the switch **150**, light **142**, speaker **143**, vibrator **154**, circuitry **146**, base **141**, conductive pad **144**, and adhesive layer **145** into a unitary and compact device configured to conform and adhere to the contours of a subject's **135** skin above the heart **137**. 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 a heartbeat may be detected. Stand-alone acoustic monitor patches of the invention may be larger to provide more space for circuitry and cover greater area over the heart **137** or an artery **6**; such stand-alone acoustic monitor patches **140** 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 acoustic monitor patches cover areas of less than about twenty square inches.

[0071] The monitor patch **140** will be able to generate visual **142**, auditory **143** and sensory **154** signals. The signal will increase and decrease in intensity based on the strength of the heartbeat. This enables the medical provider to determine if the patient's **135** heartbeat is strong, weak, or absent. The signals (light & sound) also vary in intensity with a diminishing or increased heartbeat. This enables the medical provider to determine if a heartbeat is weakening or stopping and the provider will be able to take appropriate actions and determine if a treatment is working by an increased heartbeat signal.

[0072] The acoustic monitor patch **140** 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 heartbeat and mange 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).

[0073] The invention also provides a simple continuous cardiac acoustic monitor patch **140** for checking fetal distress in pregnancy.

[0074] The acoustic monitor patch **140** of the present invention can also monitor a subject's **135** breathing and provide visual **142**, auditory **143**, and sensory **154** indicators of symptoms of distress. As with the acoustic cardiac monitoring described above, the speaker **148** can also detect sounds associated with the subject's **135** breathing. The processor **151** receives the breathing sounds from the transducer **153** and compares the received sounds to known breathing patterns stored in the processor's **151** memory. For example, sounds associated with shallow breathing may indicate an overdose state from substances such as opiates or alcohol. Also, in listening for the subject's **135** breathing, the acoustic monitor patch **140** may not detect any sound associated with known patterns of breathing. In such events, the processor **151** of the acoustic monitor patch **140** can cause the light **142**, speaker **143**, or vibrator **154** to emit distinct signals associated with respiratory distress.

[0075] FIGS. **21** and **22** show the stand-alone continuous combined acoustic and Doppler heart monitor patch **170**. As described in connection with the acoustic monitor patch **140** shown in FIG. **21**, the acoustic/Doppler monitor patch is **170** applied to the chest **136** of a patient **135** over the patient's **135** heart **137**. In this position, the acoustic/Doppler monitor **140** will be in the best position to detect the sound of a beating heart **137** and the flow of blood through the heart **137**.

[0076] FIG. **22** illustrates the parts of the combined acoustic/Doppler monitor patch **170**. The bottom of the monitor patch **140** is formed by a base **141**, which supports the circuitry **146**. Under the base **141** is an acoustic pad **144** to focus the incoming sounds of a heartbeat **157**, insulate the microphone **148** from surrounding noise, and enhance transmission and reception of the ultrasonic waves, **26** and **27**, from and to the circuitry **146** to the patient **135**, as discussed above. Beneath the conductive pad **144** is a thin adhesive layer **145** to fix the monitor patch **140** to the subject's skin, as discussed above. Mounted on the base **141** is the circuitry **146**, as described above. Over the circuitry **146** is a light **142** to indicate the strength and frequency of the detected heartbeat and pulse, as discussed above.

[0077] FIG. **22** shows more detail of the circuitry **146**. A power source **158** provides integrated power to the electronic components of the stand-alone acoustic/Doppler monitor patch **170**. A switch **152** controls power or can activate the circuitry **146** from a low-power consumption rest state. A microphone **148** receives the mechanical sound energy of a heartbeat **157**. Transmitters and receivers **22** are arrayed in or over the base **141**. The transmitters emit ultrasonic waves **26** and the receivers detect reflected waves **27**. The transducer **153** receives the electrical signals from the microphone **148** and the transmitter/receiver **22**. The reflected wave signals **27** are demodulated and analyzed by the processor **151** to determine whether the reflected wave pattern corresponds with Doppler shift signals indicative of flowing blood. In a preferred embodiment, the electrical signals from the microphone are prefiltered and amplified **156**. The transducer **153** converts the analog acoustic signals into digital signals and the digital signals are sent to the processor **153**. The processor **153** processes the digital signal to filter out unwanted noise, identify the presence or absence of sounds associated with a heartbeat **157**. The processor **151** analyzes the digital heartbeat and pulse data from the microphone **148** and transmitter/receiver **22** for frequency, strength, and arrhythmia patterns, as discussed above. Once the sound of a heartbeat and pulse are detected, the processor **151** causes the light **142** to blink in synchronization with the rhythm of the heartbeat, as discussed above. Similarly, the processor **151** may cause a speaker **143** to emit a sound, such as a beep, in synchronization with the rhythm of the heartbeat and pulse, and a vibrator **154** may vibrate in synchronization with the heartbeat and pulse to provide an indicator of the heartbeat that be detected by touch. The processor **151** will also analyze the acoustic signals **157** as well as the pulse signals for known symptoms stored in the processor's **151** memory. Using the stored values, the processor **151** will cause the light **142** to blink with an intensity corresponding to the strength or weakness of the detected heartbeat and pulse. Similarly, based on the stored values, the processor **151** will cause the speaker **143** to beep with a volume corresponding to the strength or weakness of the detected heartbeat and pulse. Additionally, based on the stored values, the processor **151** will cause the vibrator **154** to vibrate with a rhythm and strength or weakness indicative of the detected heartbeat and pulse.

[0078] 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 acoustic 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 microphone configured to receive sounds, an analog to digital converter for converting the sounds from the microphone to digital audio signals and delivering the digital audio signals to a processor, a power source providing power to the circuitry, and memory in association with the processor, wherein the processor processes the digital audio signals,

a 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, wherein the pad further comprises a sound focusing area between the upper pad surface and the lower pad surface, wherein the sound focusing area is disposed proximate the microphone, wherein the pad further comprises a sound insulating area between the upper pad surface and the lower pad surface and surrounding the sound focusing area,

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 of a chest over a heart and the patch is sized to fit on the skin over a portion of the heart, wherein the processor is adapted to detect a heartbeat or an absence of a heartbeat from the sounds received by the microphone, wherein the processor causes a heartbeat signal to be emitted indicative of the detected heartbeat, 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 heartbeat and emitting the heartbeat signal independent of any external device.

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

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

4. The stand-alone continuous acoustic heart monitor patch of claim **3** wherein the heartbeat signal further comprises a speaker to emit sound in response to the detected heartbeat.

5. The stand-alone continuous acoustic heart monitor patch of claim **4** wherein the sound emitted in response to the detected heartbeat comprises a variable sound intensity proportional to the strength of the detected heartbeat, and wherein the sound emitted in response to the detected heartbeat further comprises an emergency sound activated when the processor detects the absence of a heartbeat.

6. The stand-alone continuous acoustic heart monitor patch of claim **3** wherein the heartbeat signal further comprises a vibrator to emit a vibration in response to the detected heartbeat.

7. The stand-alone continuous acoustic heart monitor patch of claim **6** wherein the vibration emitted in response to the detected heartbeat comprises a variable vibration intensity proportional to the strength of the detected heartbeat, and wherein the vibration emitted in response to the absence of a heartbeat is an emergency vibration activated when the processor detects the absence of a heartbeat.

8. The stand-alone continuous acoustic heart monitor patch of claim **2** further comprising a switch to activate the circuitry from an inactive state.

9. The stand-alone continuous acoustic heart monitor patch of claim **8** wherein the switch is activated when the peel-away sheet is removed from the lower adhesive surface.

10. The stand-alone continuous acoustic 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.

11. The stand-alone continuous acoustic heart monitor patch of claim **1** wherein the processor is further configured to breathing by the patient or an absence of breathing from the sounds received by the microphone, and wherein the processor causes a breathing signal to be emitted indicative of the detected breathing.

12. The stand-alone continuous acoustic heart monitor patch of claim **11** wherein the processor causes an absence of breathing signal to be emitted indicative of the detected absence of breathing.

* * * * *

patsnap

专利名称(译)	具有整体视觉和听觉警报的独立连续心脏多普勒和声脉冲监测贴片以及贴片显示系统和方法		
公开(公告)号	US20190388056A1	公开(公告)日	2019-12-26
申请号	US16/508885	申请日	2019-07-11
[标]发明人	RODRIQUEZ GERARDO		
发明人	RODRIQUEZ, GERARDO		
IPC分类号	A61B8/00 A61B5/00 A61B8/02 A61B8/06 A61B8/08		
CPC分类号	A61B8/4236 A61B8/4281 A61B8/02 A61B5/6833 A61B8/065 A61B8/488 A61B5/742 A61B8/56 A61B8/0866 A61B5/026 A61B7/02 A61B8/06		
优先权	62/523765 2017-06-22 US		
外部链接	Espacenet USPTO		

摘要(译)

独立的连续心脏多普勒或听觉脉搏监测贴片可提供视觉和听觉信号，表明在人类受试者中检测到或未检测到脉搏或心跳。 本发明是具有可剥离的粘合表面的小贴剂，其被施加到受试者的皮肤上，优选在大动脉附近。 对于多普勒监护仪，贴片包括一个由导电介质形成的垫片，以增强超声波的发射和接收。 对于声学监视器，垫具有允许声音进入并将声音朝向麦克风聚焦的声音集中部分，并且垫还具有围绕声音集中部分的隔音部分。 该贴片包括一个集成电源。 多普勒贴片具有用于发送和检测反射超声波的发射器和接收器，以及用于将反射波转换为电信号的换能器。 声学贴片具有用于检测心跳声音的麦克风和用于将声能转换为电信号的换能器。 处理器分析多普勒波信号或声信号。 指示灯指示从多普勒波信号检测到的脉冲或麦克风检测到的心跳的存在和强度。 扬声器和振动器还可以指示脉冲或心跳的存在和强度。 从心脏泵出的血液中反射回来的波的多普勒效应被用来检测对象的脉搏。 处理器分析脉冲或心跳的存在，以确定血液流动或心脏跳动的频率和强度。 处理器使灯，扬声器或振动器以指示有节奏的血流或心跳频率的速率闪烁，发出蜂鸣声或振动。