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(54) **NON-INVASIVE SENSOR APPARATUS AND METHOD FOR ASSESSING CARDIAC PERFORMANCE**

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USPC ..... **600/301**; 600/508; 600/483; 600/504

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**Related U.S. Application Data**

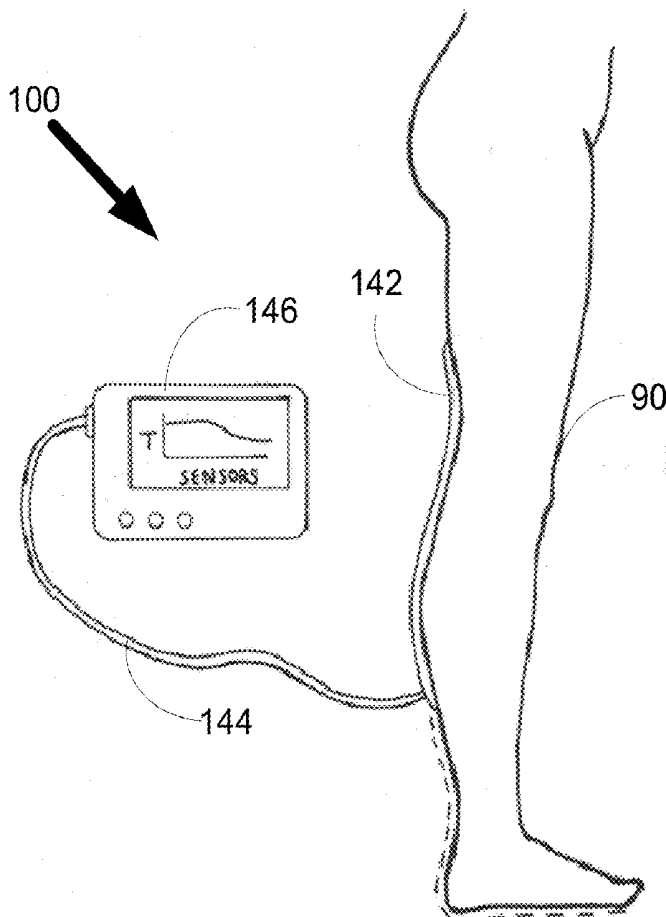
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**Publication Classification**

(51) **Int. Cl.**  
*A61B 5/0205* (2006.01)  
*A61B 5/00* (2006.01)

(57) **ABSTRACT**

Non-invasive sensor apparatus and method for assessing cardiac performance. A wide variety of different sensor components can capture sensor readings relating to patient attributes. Those sensor readings can then be compared by a processor component to derive a cardiac performance indicator relating to the patient.



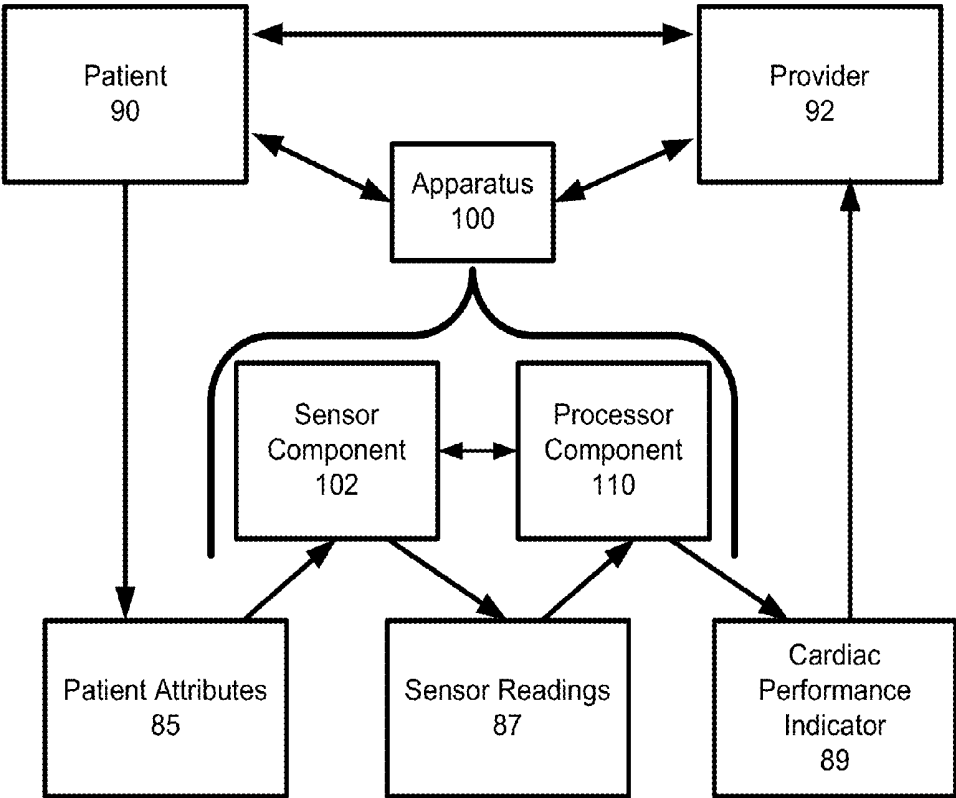


Figure 1a

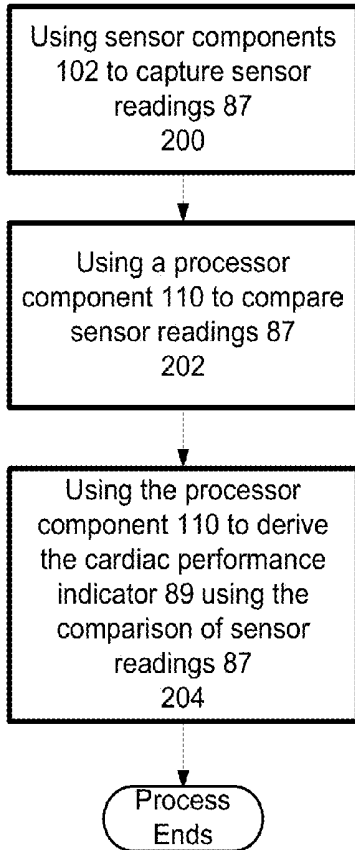


Figure 1b

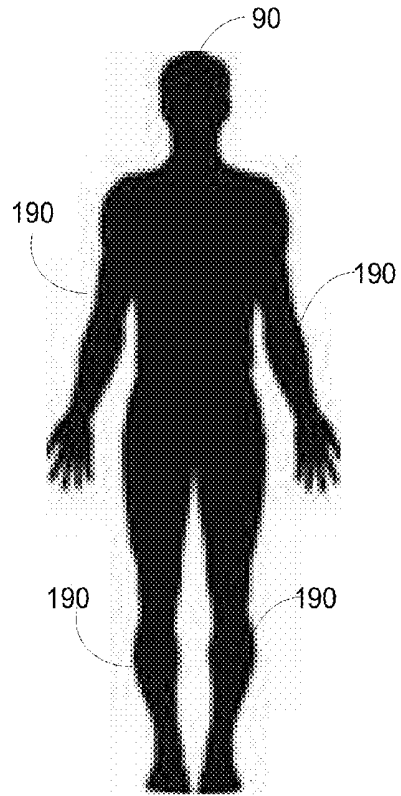


Figure 1c

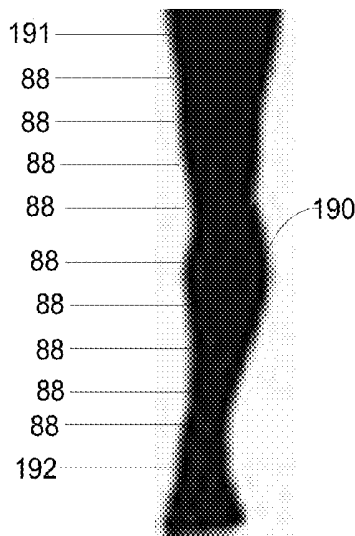


Figure 1d

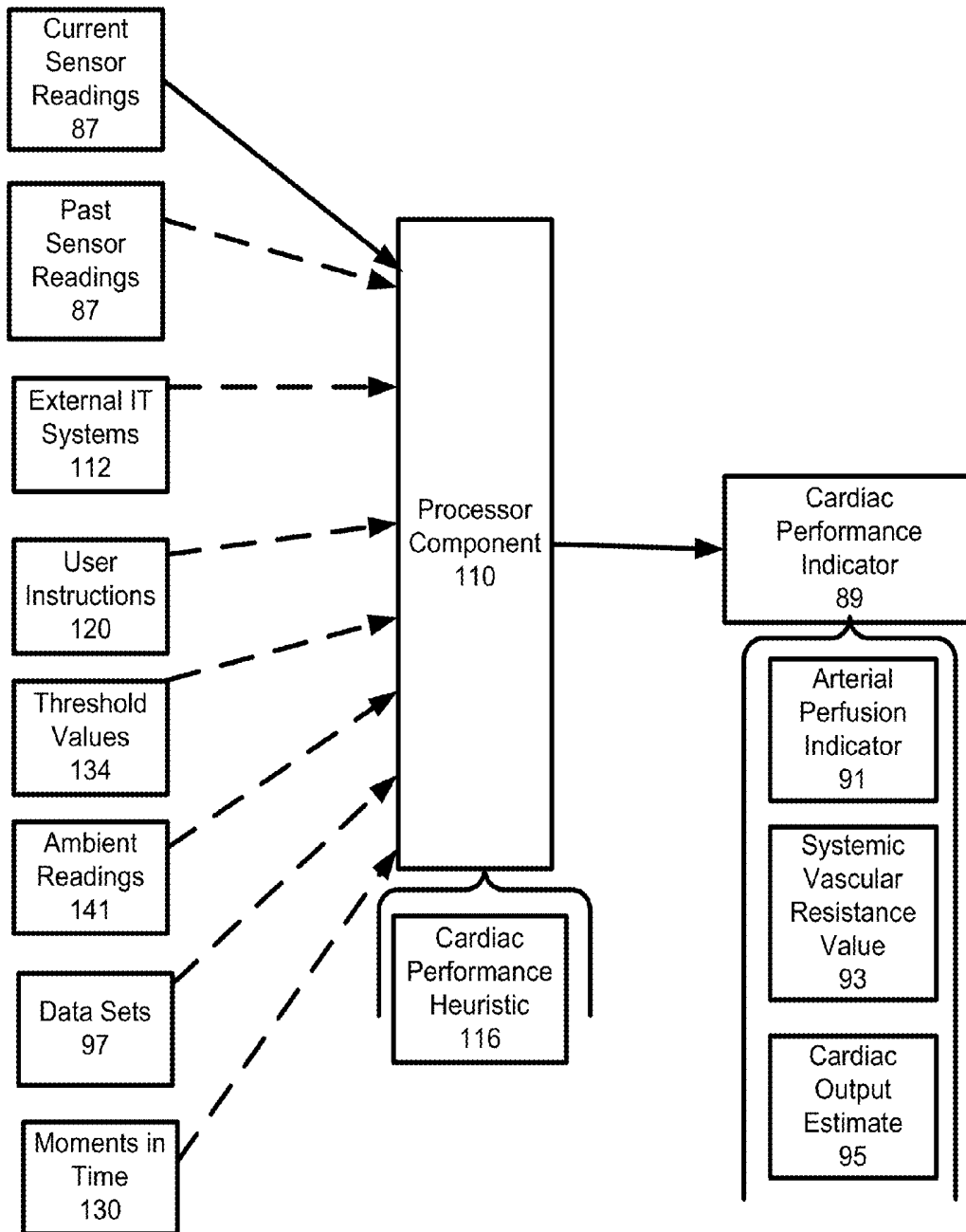


Figure 1e

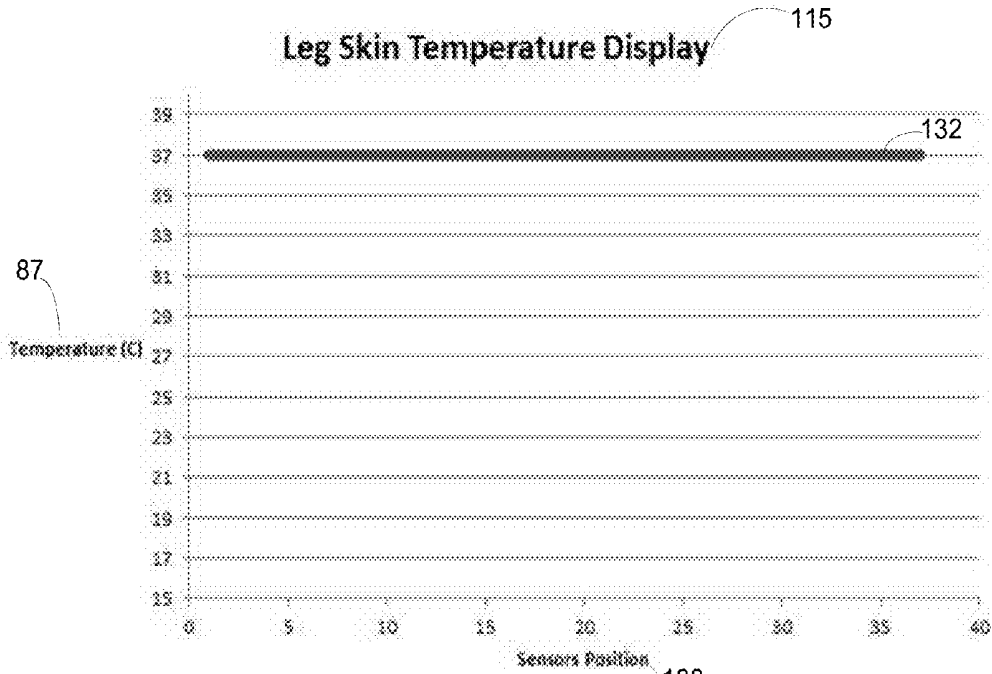


Figure 1f

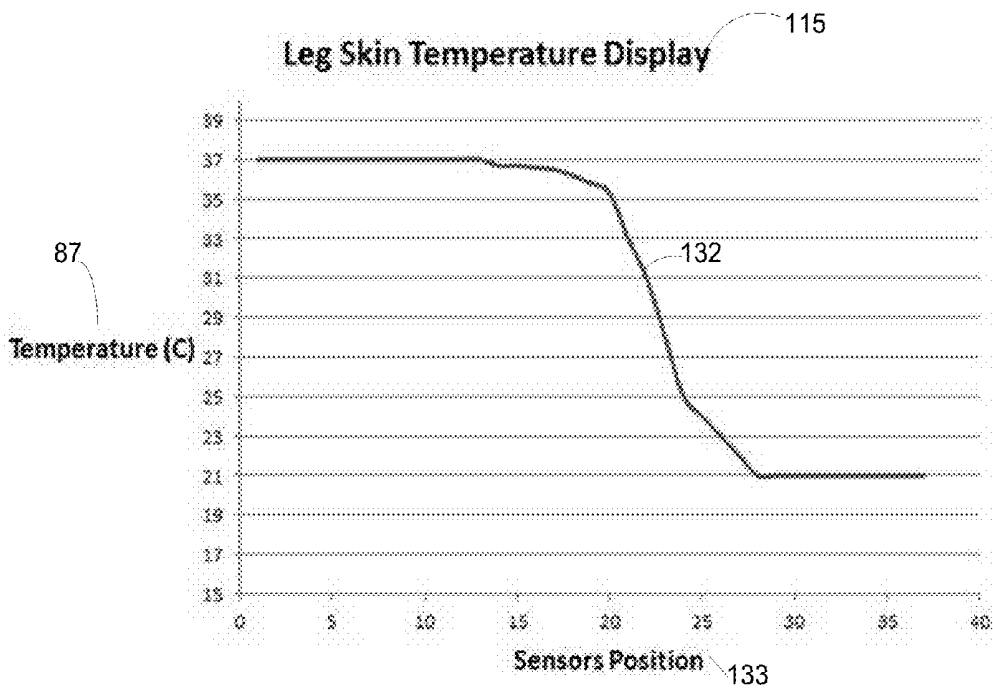
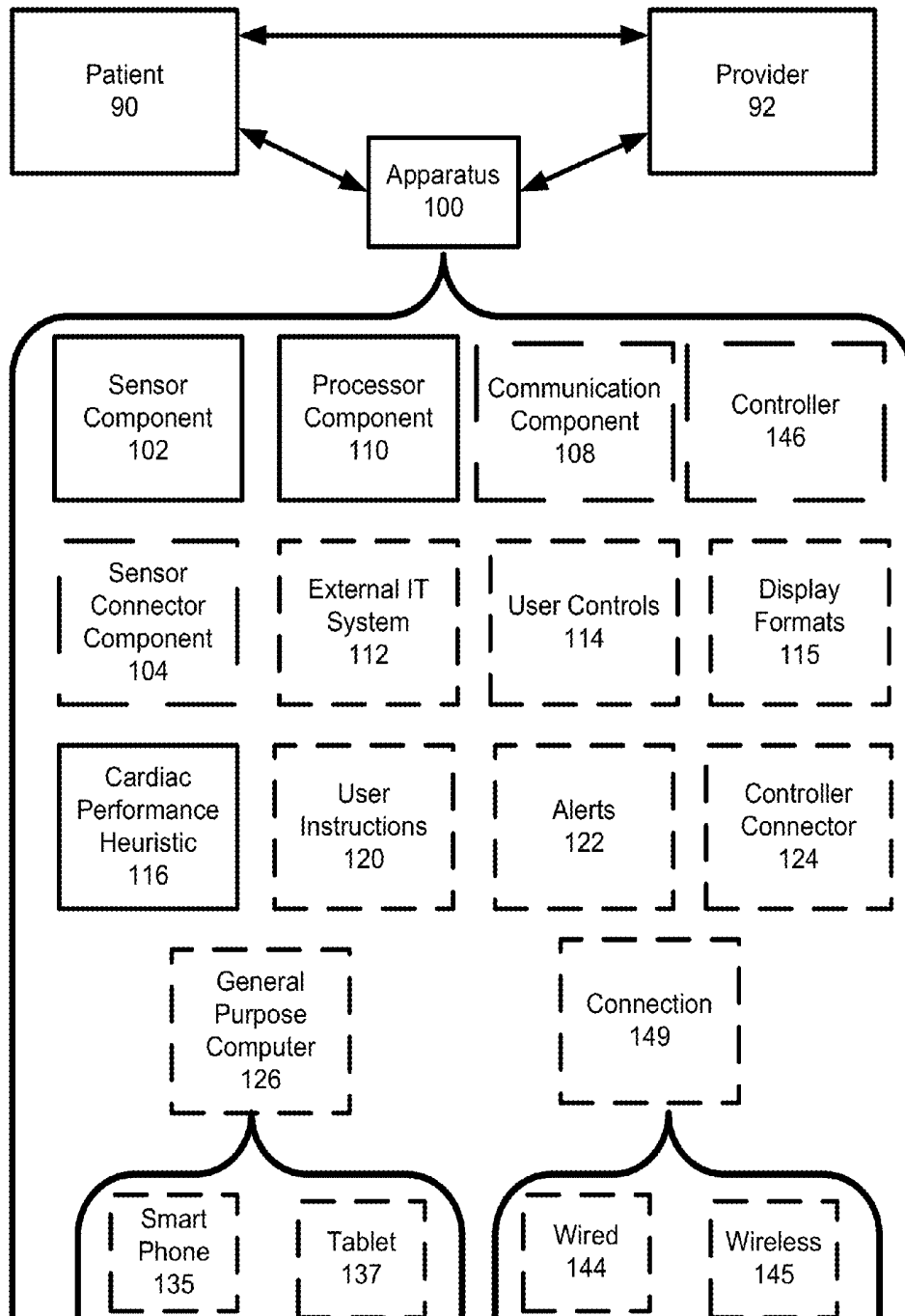
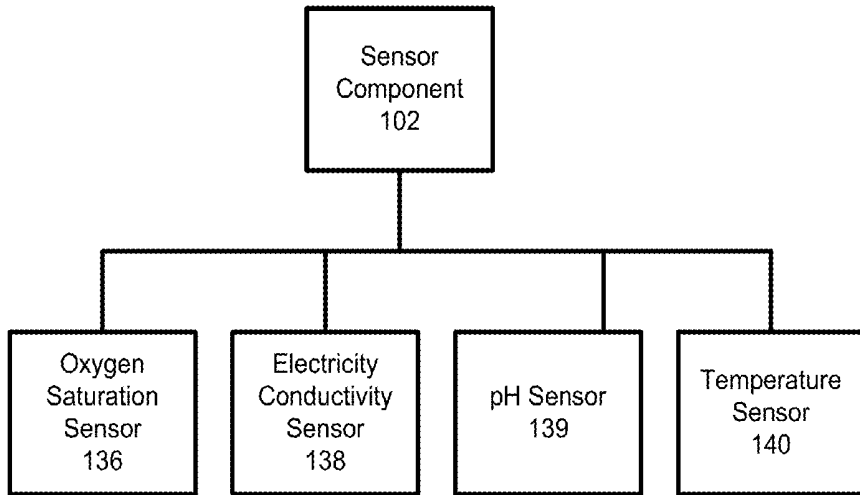


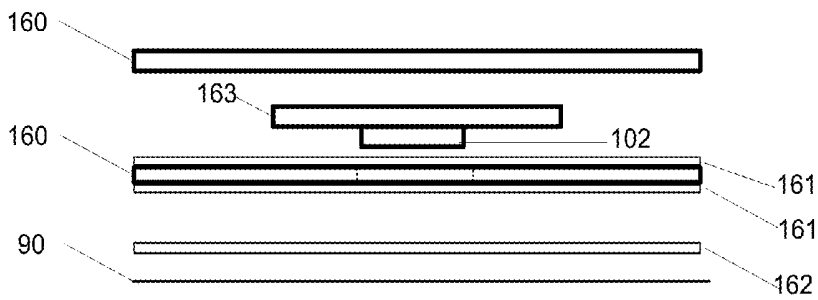
Figure 1g



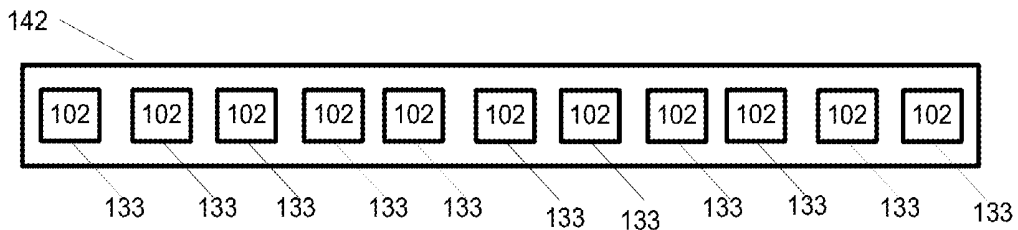
**Figure 2**



**Figure 3a**



**Figure 3b**



**Figure 3c**

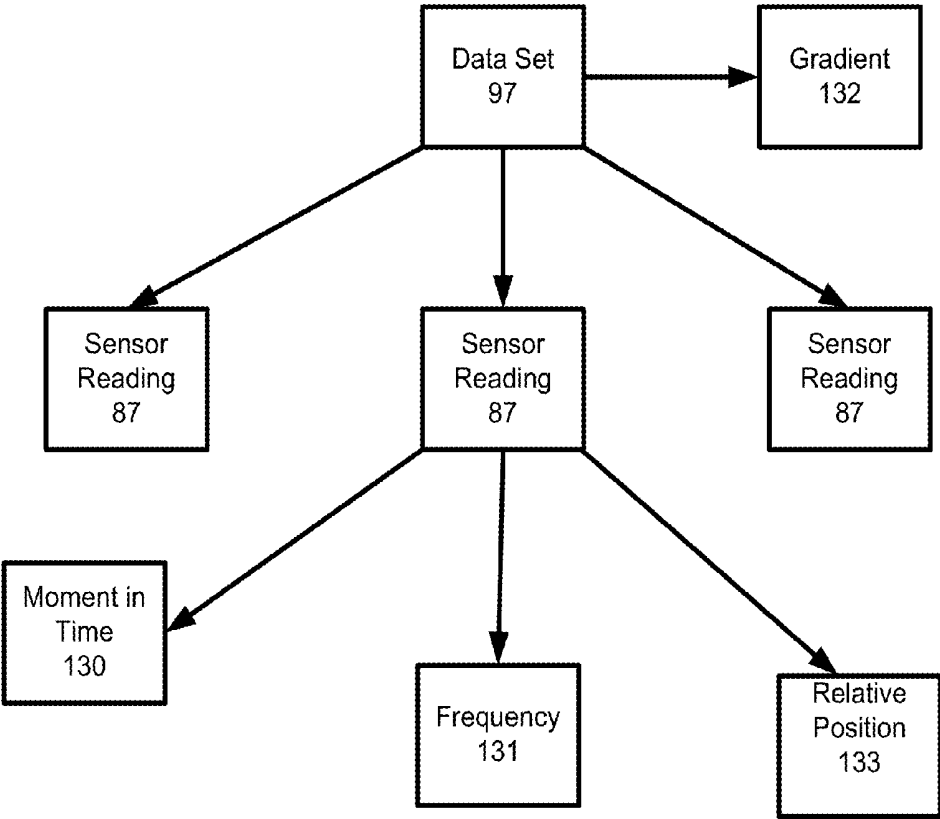


Figure 4

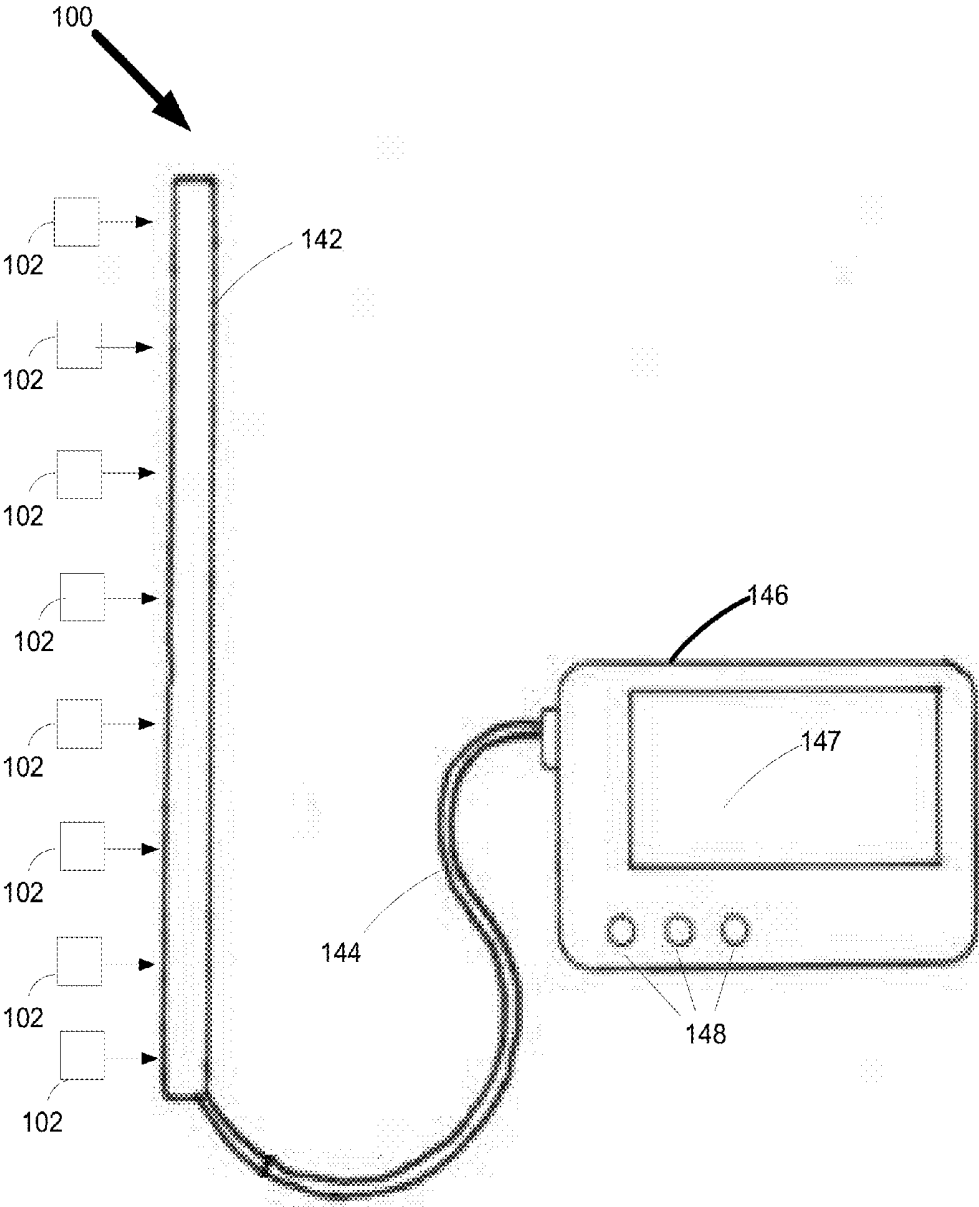


Figure 5a

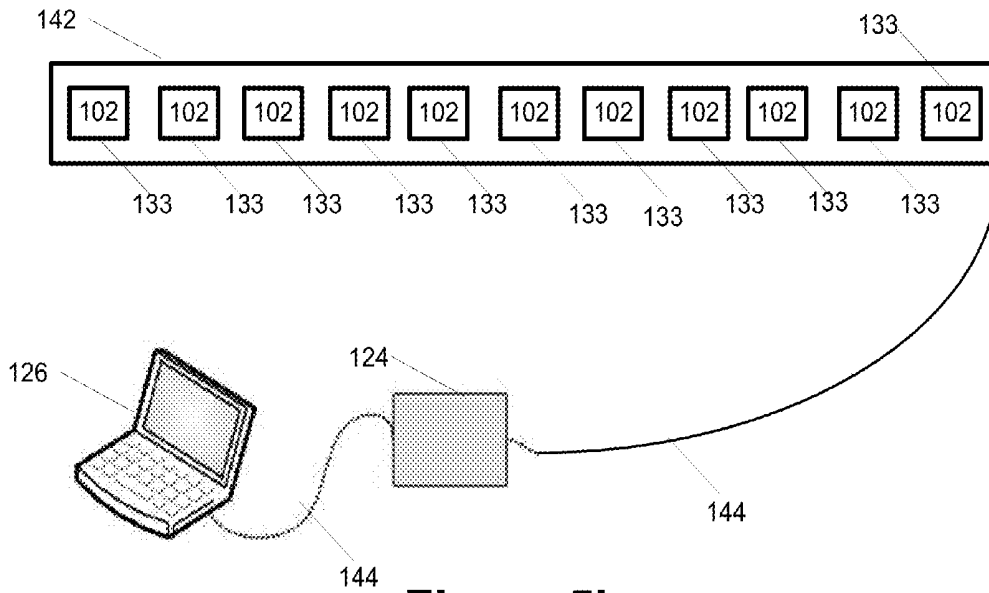


Figure 5b

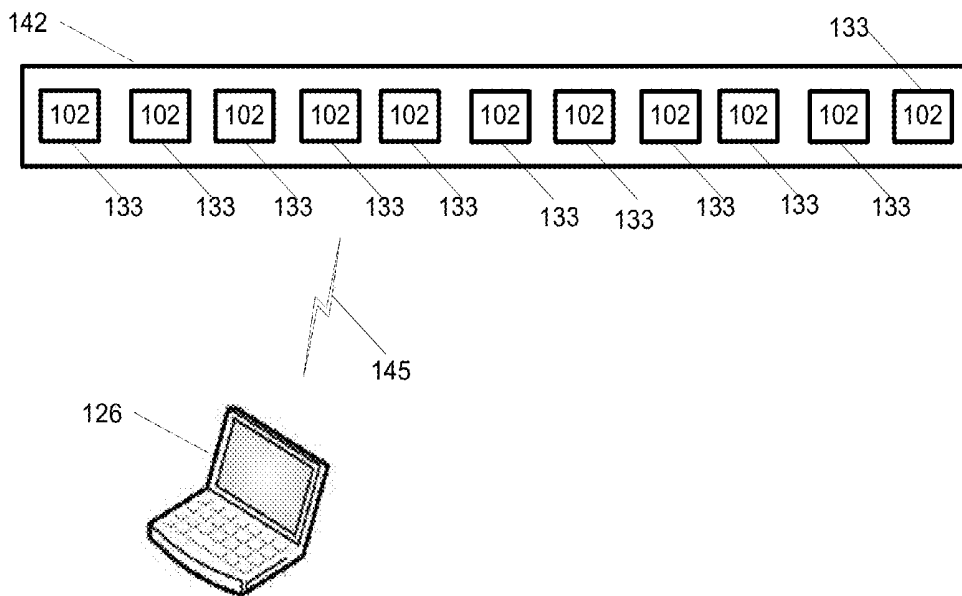


Figure 5c

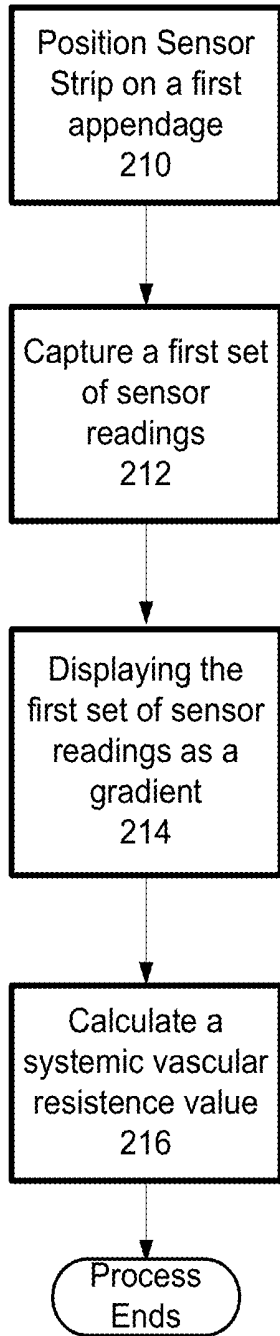


Figure 6a

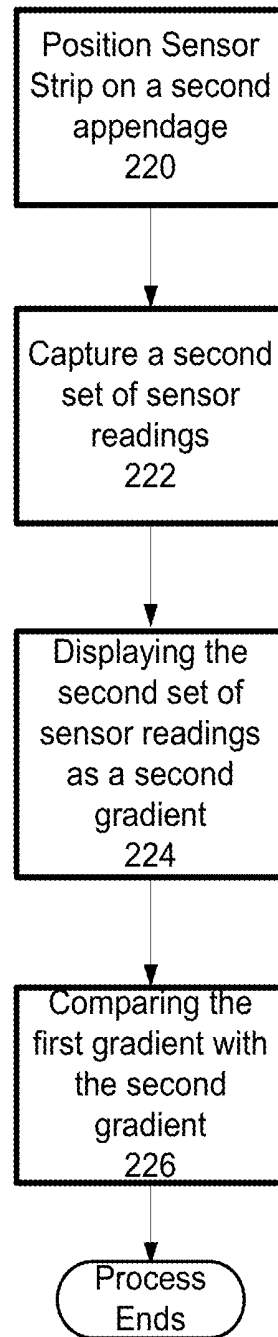


Figure 6b

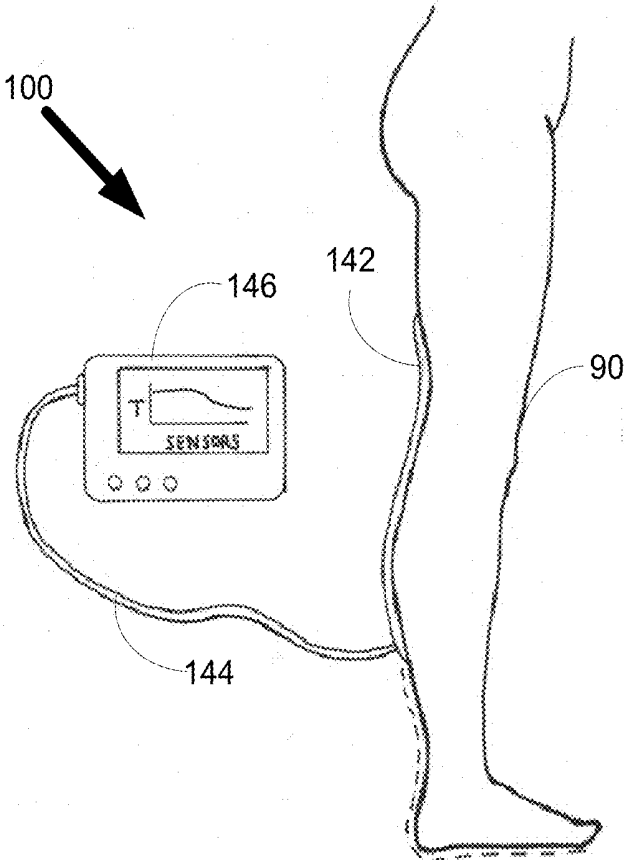


Figure 7a

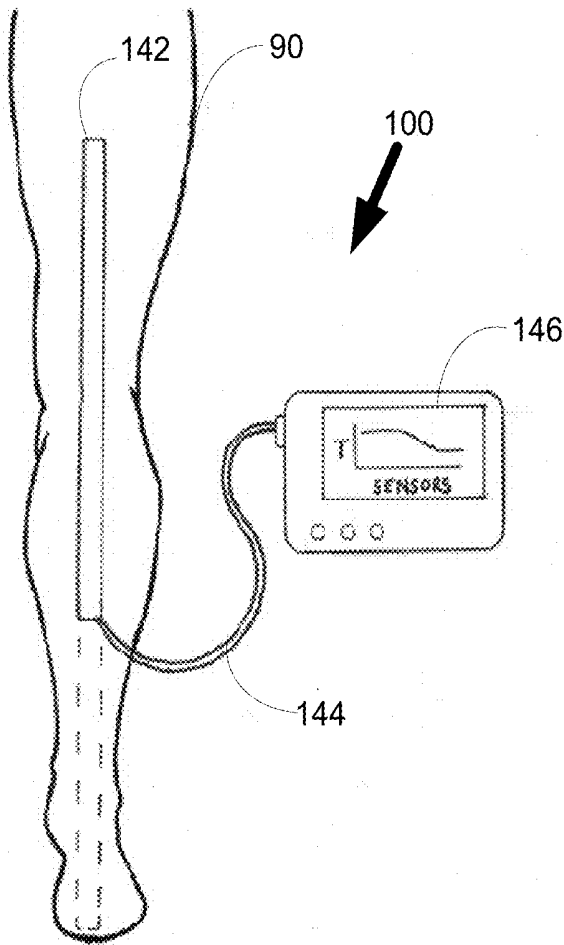


Figure 7b

## NON-INVASIVE SENSOR APPARATUS AND METHOD FOR ASSESSING CARDIAC PERFORMANCE

### RELATED APPLICATIONS

**[0001]** This utility patent application claims priority to the provisional patent application titled “SENSOR APPARATUS AND METHOD” (Ser. No. 61/701,868) filed on Sep. 17, 2012, the contents of which are hereby incorporated by reference in its entirety.

### BACKGROUND OF THE INVENTION

**[0002]** The invention is a non-invasive sensor apparatus and method for assessing cardiac performance (collectively the “apparatus”).

**[0003]** I. Importance of Cardiac Performance

**[0004]** The circulation of blood is essential for a healthy body. Blood provides organs and individual cells with the nutrients necessary to sustain life. Blood also removes cellular metabolic waste products from the body. At the center of the cardiovascular system is the heart, an organ responsible for pushing blood throughout the body. The heart functions as a pump at the center of a complex network of arteries and veins that make up the cardiovascular system. The cardiovascular system is thus responsible for the delivery of nutrients and the removal of certain wastes throughout the body. The performance of the cardiovascular system can be evaluated in terms of cardiac output.

**[0005]** Unfortunately, age, disease, trauma, and/or other ailments can hinder the distribution of blood throughout the body. Cardiovascular diseases are a serious health problem in the United States and elsewhere.

**[0006]** II. Cardiovascular Diseases Cause Death

**[0007]** According to the World Health Organization (“WHO”), cardiovascular diseases are the number one cause of death in world. An estimated 17.3 million people died of cardiovascular diseases in 2008, a number that represents 30% of all deaths occurring in that year. According to WHO estimates, the number of deaths caused by cardiovascular diseases will reach 23.4 million by 2030.

**[0008]** The Centers for Disease Control and Prevention (“CDC”) report that “[c]ardiovascular disease is the leading killer in every racial and ethnic group in America.” Many health problems in the United States are either rooted in or manifested as cardiovascular disease. The most common type of heart disease in the United States is coronary artery disease (“CAD”). CAD occurs when plaque builds up in the arteries that supply blood to the heart. This can cause the arteries to narrow over time in a process called atherosclerosis. Plaque buildup can also cause chest pain or discomfort resulting from the inadequate supply of blood to the heart muscle, a condition known as angina. Over time CAD can lead to an irregular heartbeat, a condition known as arrhythmia, and even heart failure.

**[0009]** III. Inadequacy of Non-Invasive Techniques

**[0010]** The life of every human being depends on the continuous presence of sufficient cardiac performance. Unfortunately, prior art tests of cardiac performance such as the insertion of a Swan-Ganz thermal dilution catheter into the pulmonary artery, and other similar tests are invasive, time consuming, and expensive. As a result, many patients with ultimately serious conditions go untested until after the underlying problems become severe.

**[0011]** The diagnosis and treatment of patients would benefit from a non-invasive technique for assessing cardiac performance.

### SUMMARY OF THE INVENTION

**[0012]** The invention is a non-invasive sensor apparatus and method for assessing cardiac performance (collectively the “apparatus”).

**[0013]** The apparatus can utilize non-invasive sensor readings captured from the skin of the patient to generate an indicator of the patient’s cardiac performance. Different embodiments of the apparatus can involve a different number of sensors, different sensor types, different sensor configurations, and different display and processor capabilities.

**[0014]** A wide range of different types of sensor readings can be utilized, including but not limited to temperature, pH, electrical connectivity, and oxygen saturation.

**[0015]** Different embodiments of the apparatus can integrate and communicate with external devices to different degrees, with some embodiments of the apparatus being intended to operate as stand alone devices and other embodiments intended to communicate with a potential range of general purpose and/or process specific devices.

**[0016]** The apparatus can be utilized on a wide variety of different parts of the body of the patient, although it may be particularly desirable to capture sensor readings on the arms or legs because of the ability to compare and contrast sensor readings taken at the core of the body with sensor readings taken at the extremities of an appendage.

**[0017]** A wide variety of different cardiac performance heuristics can be used to calculate a wide variety of different cardiac performance indicators. For example, an arterial perfusion heuristic could be used to generate an arterial perfusion indicator.

**[0018]** In many embodiments of the apparatus, a gradient of sensor readings with respect to sensor location on the body will be the primary input for deriving the cardiac performance indicator. In alternative embodiments, additional factors such as sensor readings over time, other patient data accessible on medical records, ambient temperature and other sensor readings at the location of the sensors, and/or operating parameters inputted on behalf of the provider can impact the way that a cardiac performance heuristic will generate a cardiac performance indicator.

### BRIEF DESCRIPTION OF THE DRAWINGS

**[0019]** Many features and inventive aspects of the apparatus are illustrated in the following drawings:

**[0020]** FIG. 1a is a block diagram illustrating an example of interaction between a patient and healthcare provider using the apparatus, and some of the different components and data elements that can be incorporated into the apparatus.

**[0021]** FIG. 1b is a flow chart diagram illustrating an example of the apparatus being used to derive a cardiac performance indicator from sensor readings captured by sensor components.

**[0022]** FIG. 1c is a diagram illustrating an example of a human being with four appendages as a patient.

**[0023]** FIG. 1d is a diagram illustrating a close-up view of an appendage displayed in FIG. 1c.

**[0024]** FIG. 1e is an input-output diagram illustrating an example of the different inputs that can impact the cardiac performance indicator generated by the apparatus.

[0025] FIG. 1*f* is an example of a display format for a gradient in which the cardiac performance indicator indicates healthy cardiac performance.

[0026] FIG. 1*g* is an example of a display format for a gradient in which the cardiac performance indicator indicates unhealthy cardiac performance.

[0027] FIG. 2 is a block diagram illustrating an example of interaction between a patient and healthcare provider using the apparatus, and some of the different components and data elements that can be involved in the functionality of the apparatus.

[0028] FIG. 3*a* is a hierarchy diagram illustrating an example of different categories of sensor components that can be included in different embodiments of the apparatus.

[0029] FIG. 3*b* is a side view diagram illustrating an example of a sensor component and some accompany components that can provide for securing the sensor component on a patient location.

[0030] FIG. 3*c* is a block diagram illustrating an example of a sensor strip.

[0031] FIG. 4 is a data diagram illustrating the relationships between a data set, the sensor readings that can make up a data set, and some of the attributes that can relate to a sensor reading.

[0032] FIG. 5*a* is diagram illustrating an example of an apparatus that has a dedicated special purpose controller attached.

[0033] FIG. 5*b* is a diagram illustrating an example of an apparatus that uses an interface device to connect a general purpose computer to the apparatus.

[0034] FIG. 5*c* is a diagram illustrating an example of an apparatus that can interact with a general purpose computer without the inclusion of an interface device.

[0035] FIG. 6*a* is a flow chart diagram illustrating an example of a process by which a systemic vascular resistance value is calculated using sensor readings from a temperature sensor.

[0036] FIG. 6*b* is a flow chart diagram illustrating an example of two gradients being compared/contrasted with each other to selectively derive the applicable cardiac performance indicator.

[0037] FIG. 7*a* is an environmental diagram illustrating an example of the apparatus in the context of temperature sensors being positioned on a leg of the patient.

[0038] FIG. 7*b* is an environmental diagram illustrating an example of the apparatus in the context of temperature sensors being positioned on a leg of the patient.

## DETAILED DESCRIPTION

[0039] The invention is a non-invasive sensor apparatus and method for assessing cardiac performance (collectively the “apparatus”).

### I. OVERVIEW

[0040] FIG. 1*a* is a block diagram illustrating an example of interaction between a patient 90 and healthcare provider 92 using the apparatus 100, and some of the different components and data elements that can be incorporated into the apparatus 100.

[0041] Patients 90 possess patient attributes 85 which can be detected by a sensor component 102 in the form of a sensor reading 87. A processor component 110 can derive a cardiac

performance indicator 89 by analyzing the sensor readings 87 captured by the sensor component 102.

[0042] The human body is a collection of organ systems working together to perform the tasks and meet the needs of the body. Blood provides oxygen, nutrients, and enzymes to the body. It also carries away cellular metabolic waste products. Blood flow is managed by the vascular system, a network of arteries and veins through which the heart pumps blood.

[0043] Sufficient cardiac output is necessary to sustain life. The impact of insufficient cardiac output can manifest itself in a variety of ways, particularly in the extremities of the body such as legs and arms of a human being. These manifestations, if promptly detected, can serve as a valuable advance warning to providers 92 and patients 90 alike. The early symptoms of insufficient cardiac output can serve as a valuable opportunity that can be exploited for the betterment of patients 90. The symptoms of insufficient cardiac output can be detected in a non-invasive manner when the patient 90 is not suffering from severely insufficient cardiac output, and such early detection can maximize the possibility that steps can be taken to avoid more advanced implications.

[0044] The apparatus 100 can utilize sensor readings 87 to non-invasively derive important cardiac performance indicators 89 where prior art techniques would require far more invasive, time consuming, expensive, and inconvenient detection techniques.

[0045] A. The Apparatus is a Way for Providers to Interact with Patients

[0046] As illustrated in FIG. 1*a*, the apparatus 100 is a means by which providers 92 interact with their patients 90. The functionality of the apparatus 100 is intended to be part of the delivery system of healthcare to a patient 90 by one or more providers 92.

[0047] 1. Patients

[0048] A patient 90 is typically a human being, although the apparatus 100 (or alternative variations thereof) can also be used in the treatment of potentially any organism, particularly other mammals.

[0049] In the context of human beings, patients 90 can vary widely in terms of age, size, gender, weight, medical status, and other attributes.

[0050] 2. Providers

[0051] A provider 92 is typically a healthcare professional such as a physician. In many contexts, the provider could also be a physician’s assistant, nurse, technician, paramedic, home health care provider, family or friend that provides care, or other person who assists the physician. In some contexts, patients 90 may act as their own health care providers 92.

[0052] The range of potential providers 92 who may find the apparatus 100 desirable is commensurate with the broad range of contexts that the apparatus 100 can be used. For example, in the context of treating animals, the provider 92 could be a veterinarian or veterinarian’s assistant. In the context of human patients 90, the apparatus 100 can be used in the context of a variety of different treatment protocols and a variety of different medical conditions.

[0053] B. The Apparatus is Comprised of Component Parts

[0054] As illustrated in FIG. 1*a*, the apparatus 100 is comprised of a sensor component 102 for the capturing of sensor readings 87 and a processor component that analyzes those sensor readings 87 to derive a cardiac performance indicator 89.

**[0055]** 1. Sensor Component

**[0056]** A sensor component **102** is a means by which information in the form of sensor readings **87** is provided to a processor component **89** for analysis leading to the deriving of a cardiac performance indicator **89** by the apparatus. Different embodiments of the apparatus **100** can involve different numbers of sensor components **102** placed at a different number of locations on a patient **90**. By comparing/contrasting sensor readings **87** from different locations of the patient **90**, inadequate cardiac output can be detected by the apparatus **100**.

**[0057]** Different embodiments of the apparatus **100** can also involve different types of sensor components **102** that measure different types of patient attributes **85**. As illustrated in FIG. **3a**, the sensor components **102** used by the apparatus **100** can include temperature sensors **140** that detect cardiac output issues through differences in skin temperature, pH sensors **139** that detect cardiac output issues through differences in acidity levels, electricity conductivity sensors **138** that detect cardiac output issues through differences in electrical conductivity, oxygen saturation sensors **136** which detect cardiac output issues through differences in oxygen saturation, as well as other types of sensors.

**[0058]** 2. Processor Component

**[0059]** Returning to FIG. **1a**, a processor component **110** is the mechanism by which the sensor readings **87** of the sensor components **102** are utilized to derive cardiac performance indicators **89**. In some embodiments, the processor component **110** may simply be means to organize the data of the sensor readings **87** into a meaningful display. In other embodiments, more advanced processing can be performed.

**[0060]** Computing power can be used to transform the apparatus **100** from a mere reporting device to a device that can be configured to address certain conditions and operating parameters. In some embodiments of the apparatus **100**, the processor component **110** has the capacity to function as a general purpose computer, i.e. possesses the ability to run software, install updates, and store data.

**[0061]** C. Apparatus as a Processor of Data

**[0062]** The purpose of the apparatus **100** is to assess the cardiac performance status of the patient **90** that can be detected through non-invasive sensor readings **87** captured from the skin of the patient **90**. Sensor readings **87** can relate to a wide variety of different patient attributes **85** that can be relevant in assessing the cardiac performance of the patient **90**, i.e. deriving cardiac performance indicators **89** pertaining to the patient **90**.

**[0063]** 1. Patient Attributes

**[0064]** A patient attribute **85** is potentially any attribute relating to the patient **90** that can be relevant to assessing the cardiac performance of the patient **90**. Some patient attributes **85** can be captured in the form of sensor readings **87**, such as temperature measurements, pH levels, electricity conductivity metrics, oxygen saturation levels, and other detectable phenomenon. Other types of patient attributes **85** such as medical history, age, etc. may not be detectable by a sensor component **102** but may still be able to be integrated into the processing of the apparatus **100** through a variety of information technology mechanisms.

**[0065]** 2. Sensor Readings

**[0066]** A sensor reading **87** is the output of a sensor component **102** that relates to one or more patient attributes **85**. Sensor readings **87** are the primary means by which the pro-

cessor component **110** is provided with sufficient information to generate cardiac performance indicators **89**.

**[0067]** 3. Cardiac Performance Indicators

**[0068]** A cardiac performance indicator **89** is the output of the apparatus **100**. A cardiac performance indicator **89** is an indication of cardiac performance (i.e. health) of the patient **90**. Such indicators **89** can vary from the mere display of data in a usable form (see FIGS. **1f** and **1g**) to complex outputs involving a potentially wide variety of different inputs beyond sensor readings **87** (see FIG. **1e**). As illustrated in FIG. **1e**, there are different types of cardiac performance indicators **89** including but not limited to arterial perfusion indicators **91**, systematic vascular resistance values **93**, and cardiac output estimate **95**. Some embodiments of the apparatus **100** can provide users with multiple types of cardiac performance indicators **89**, as well as the ability to selectively influence how such indicators **89** are derived and displayed.

**[0069]** D. Process for Using the Apparatus

**[0070]** FIG. **1b** is a flow chart diagram illustrating an example of the apparatus **100** being used by a provider **92** or other user to create a cardiac performance indicator **89**.

**[0071]** At **200**, sensor components **102** are used to capture sensor readings **87** from the patient **90**.

**[0072]** At **202**, a processor component **110** is used to compare the sensor readings **87** captured at **200** above. In some embodiments of the process, current sensor readings **87** may also be compared with prior sensor readings **87**, sensor readings **87** captured from other locations on the patient **90**, and other sources of information (see FIG. **1e**).

**[0073]** Returning to FIG. **1b**, at **204**, the processor component **110** is then used to derive the cardiac performance indicator **89** on the basis of the sensor readings **87** and potentially other inputs to the processor component **110**.

**[0074]** E. Locations on the Body

**[0075]** Virtually any location on the body of the patient **90** can be used to position a sensor component **102** for the purposes of capturing sensor readings **87**. A human being is a collection of organ systems working together to perform the tasks and meet the needs of the body. Blood flows throughout the body, and thus the implications of insufficient cardiac performance are potentially detectable in a wide variety of different locations in a wide variety of different ways. However, for the purposes of evaluating cardiac performance problems through non-invasive sensor readings **87**, some locations on the body are better suited than others to assist providers **92** in identifying problems as soon as possible.

**[0076]** FIG. **1c** is a diagram illustrating a human being as the patient **90**. Like most human beings, the illustration discloses four large appendages **190** or limbs in the form of two legs and two arms. In many embodiments of the apparatus **100**, locations on an appendage **190** such as an arm or leg will be the desirable location for the apparatus **100** to be used because such locations will highlight or even amplify the impact of relatively small differences in cardiac performance. **[0077]** FIG. **1d** is a close-up view of one of the legs illustrated in FIG. **1c**. As illustrated in the figure, numerous potential locations **88** on the patient **90** exist for the positioning of sensor components. As illustrated in FIG. **1d**, many potential locations **88** for sensor components **102** can exist between a core location **191** of the appendage **190** (i.e. a location close to the torso) and an extremity location **192** on the other end of the appendage **190**.

**[0078]** In many embodiments of the apparatus **100**, positioning sensors components **102** from a core location **191** to

an extremity location **192** will provide the best opportunity for early non-invasive detection of cardiac performance problems.

[0079] E. Input Factors that can Influence the Resulting Output

[0080] FIG. **1e** is an input-output diagram illustrating an example of the different inputs that can impact the cardiac performance indicator **89** generated by the apparatus **100**. As illustrated in FIG. **1e**, there are a wide variety of inputs that can influence the output of the apparatus **100**. Similarly, there is also a wide variety of different cardiac performance indicators **89** that can be generated as outputs by the apparatus.

[0081] The processor component **110** of the apparatus **100** can use one or more different cardiac performance heuristics **116** to generate cardiac performance indicators **89** (i.e. outputs) from the sensor readings **87** and other form of inputs indicated in the Figure.

[0082] 1. Inputs

[0083] The different types of inputs that can impact the deriving of the cardiac performance indicator **89** include but are not limited to: (a) current sensor readings **87** from the current locations **88** of the sensor components **102** for the apparatus **100**; (b) past sensor readings **87**; (c) external IT systems **112** with access to data relating to the patient **90**; (d) user instructions **120** made available to the apparatus **100** by a provider **92** or in some instances even a patient **90**; (e) threshold values **134** that may or may not be individually tailored to the patient **90**; (f) ambient readings **141** of the sensor components **102** in an effort to avoid false positive and false negative results; and (g) data sets **97** that potentially include data from multiple apparatuses **100** taken from multiple locations **88** over multiple moments in time **130**.

[0084] 2. Outputs

[0085] The outputs of the apparatus **100** can vary widely from embodiment to embodiment both in terms of substantive processing as well as with respect to presentation.

[0086] a. Substantive Variations

[0087] As illustrated in FIG. **1e**, the different embodiments of cardiac performance indicators **89** can include arterial perfusion indicators **91**, systemic vascular resistance values **93**, cardiac output estimates **95**, and other metrics which are discussed in greater detail below.

[0088] b. Presentation Variations

[0089] FIGS. **1f** and **1g** illustrate examples of sensor readings **87** displayed graphically in a display format **115** as gradients **132**.

[0090] The Y-axis in both illustrations pertains to sensor readings **87**, and in these two instances, the sensor readings **87** are temperature measurements. The X-axis in both illustrations pertains to a relative position **133** of the sensor components **102**. Position #1 pertains to a core location **191** on an appendage **190** while Position #40 pertains to an extremity location **192**.

[0091] In FIG. **1f** the gradient **132** embodying the sensor readings **87** constitutes a straight horizontal line indicating the blood flow at the extremity location **192** is no different than the blood flow at the core location **191**. The cardiac performance illustrated in FIG. **1f** is that of good health.

[0092] In contrast, the cardiac performance illustrated in FIG. **1g** is that of poor cardiac performance. The gradient **132** in FIG. **1g** slopes significantly downward as the locations **88**

get further and further from the core location **191**. The differences between the core location **191** and the extremity location **192** are severe.

## II. ALTERNATIVE EMBODIMENTS

[0093] No patent application can disclose all of the potential embodiments of an invention. In accordance with the provisions of the patent statutes, the principles and modes of operation of the apparatus are explained and illustrated in certain preferred embodiments. However, it must be understood that the apparatus may be practiced otherwise than is specifically explained and illustrated without departing from its spirit or scope.

[0094] The description of the apparatus provided below should be understood to include all novel and non-obvious combination of elements described herein, and claims may be presented in this or a later application to any novel non-obvious combination of these elements. Moreover, the foregoing embodiments are illustrative, and no single feature or element is essential to all possible combinations that may be claimed in this or a later application.

## III. DETAILED DESCRIPTION OF APPARATUS AND COMPONENTS

[0095] FIG. **2** is a block diagram illustrating an example of some of the different components and data elements that can be involved in the functionality of the apparatus **100**. The apparatus **100** can be comprised of a wide variety of different components and involve a wide variety of different types of data. Optional components are indicated by the presence of dotted lines.

[0096] A. Apparatus

[0097] The apparatus **100** can be used in a variety of different contexts, but is typically used as part of a broader set of interactions between the patient **90** and the provider **92**. As indicated by the various arrows in FIG. **2**, the apparatus **100** can directly interact with both the patients **90** and providers **92**. For example, the apparatus **100** can be positioned on the patient **90** (typically on an appendage **190** such as a leg or arm) to capture readings **87** from the patient **90**. The apparatus **100** can provide the resulting information to the providers **92** in a variety of different ways.

[0098] The original inspiration for the apparatus **100** was to proactively identify circulatory problems by looking for differences in temperature at different locations **88** on a patient **90**. Temperature measurements can be evaluated in a variety of different ways, including but not limited to changes in temperature over time, singular instances of temperature below a certain threshold value **134** (i.e. abnormal temperature), and/or hybrid approaches thereof. By way of example, if the temperature drops at a certain point in the leg or arm of a patient **90**, there could be a circulatory problem at that location **88** that needs to be investigated and addressed.

[0099] Different embodiments of the apparatus **100** can involve different configurations of components. For example, in some embodiments the apparatus **100** can be used to identify a temperature gradient **132** while in another embodiment some other metric is the focal point of attention. In still other embodiments, entire arrays of different patient attributes **85** (including specific combinations of attributes) can serve as the focal point for the capture of data by sensor components **102**. Processing by the apparatus **100** can utilize potentially any raw sensor measurement as well as any metric that can be

derived from a raw sensor measurement. In some embodiments of the apparatus 100, the apparatus can access inputs for processing data that are captured by applications or systems outside the apparatus.

[0100] Different embodiments of the apparatus 100 can involve different degrees of automated processing that are triggered by the sensor data captured by the apparatus 100. For example, processing of the captured sensor measurements could be limited to simply displaying the data in some embodiments of the apparatus 100. In other embodiments, various heuristics 116 can be performed by a processor in the apparatus 100 itself or by other instrumentation downstream from the apparatus 100. For example, the apparatus 100 could be configured to provide certain notifications in certain contexts to providers 92 and patients 90 alike. The wide variety of different triggering events for such automated notifications can be as virtually limitless as the different types of data that can be useful to the monitoring and treatment of patients 90.

[0101] The apparatus 100 can be used in a variety of different contexts, including an emergency room (ER), an intensive care unit (ICU), a critical care unit (CCU), surgical recovery, other hospital settings, ambulances, nursing care facilities, physician offices, and the homes of patients 90.

[0102] B. Sensor Component

[0103] The apparatus 100 can use multiple sensor components 102. The apparatus 100 can incorporate a wide variety of different sensor components 102 with a wide variety of different sensor attributes.

[0104] a. Type of Measurement

[0105] Sensor components 102 can vary widely in terms of the type of data that is captured. Temperature is a common example of a type of data that can be captured by sensor components 102 incorporated into the apparatus 100. In alternative embodiments, other types of sensor components 102 can be used. In some embodiments of the apparatus 100, a wide variety of different types of sensor components 102 can be incorporated into the apparatus 100.

[0106] As illustrated in FIG. 3a, sensor components 102 can measure oxygen saturation, electricity conductivity, pH levels, temperature and potentially other phenomenon. As illustrated in FIG. 4, a sensor reading 87 captured by a sensor can also include information relating to a moment in time 130, frequency 131, and a relative position 133 of the sensor component 102 with respect to other sensor components 102.

[0107] b. Frequency

[0108] Some sensor components 102 can capture sensor readings 87 on a continuous basis. Other sensor components 102 can be configured to capture sensor readings 87 at a specific frequency. In some embodiments of the apparatus 100, the frequency 131 of sensor readings 87 can be automatically adjusted by programming logic in the apparatus 100 that is selectively influenced by relevant attributes pertaining to the patient 90, the sensor component 102, and/or other factors.

[0109] c. Locations and/or Relative Positions

[0110] In some embodiments of the apparatus 100, it may be important for the apparatus 100 to know the precise location 88 of a particular sensor component 102 with respect to the body of the patient 90. In other embodiments, the relative position 133 of a particular sensor component 102 with respect to other sensor components 102 is all that is required. For example, in the sensor-strip 142 embodiment of the apparatus 100 illustrated FIG. 5a, all that is needed is the relative

position of each sensor component 102 in order to generate the data displays as illustrated in FIGS. 1f and 1g.

[0111] C. Sensor Connector Component

[0112] Returning to FIG. 2, the apparatus 100 can include a sensor connector component 104, such as a sensor strip 142 that encompasses and/or includes the various sensors 102. In other embodiments of the apparatus 100, the sensor connector component 104 is virtually any structure or mechanical configuration that is used to secure the position of the sensor components 104.

[0113] D. Processor Component

[0114] The processor component 110 is the device that performs the processing logic of the apparatus 100. The range of processing performed by the apparatus 100 can be as basic supporting the electronic display of sensor readings 87 to the performance of advanced cardiac performance heuristics 116 that can selectively create cardiac performance indicators 89 based on a wide range of different inputs (see FIG. 1e).

[0115] Computing power can be used to transform the apparatus 100 from a mere reporting device to a device that can be configured to address certain conditions and operating parameters. In some embodiments of the apparatus 100, the processor component 110 has the capacity of function as a general purpose computer 126, i.e. possesses the ability to run software, install updates, and store data. In some embodiments of the apparatus 100, the processor component 110 can be a general purpose computer 126 that is connected to (see FIG. 5b) or in communication with (see FIG. 5c) the sensor components 102. The apparatus 100 can be implemented in such a manner as to allow users to interact with the apparatus 100 through a smart phone 135, tablet 137, or other similar general purpose computer 126.

[0116] In some embodiments, the processor component 110 will be the same device as the communications component 110, such as a controller 146 and it will include: a variety of user controls 114; the ability invoke various heuristics 116; the ability to create, store and submit user instructions 120; the ability to create an automated alert 122; and the ability to export output data to external systems and applications such as external IT systems 112.

[0117] E. Communication Components and Controllers

[0118] A communication component 108 is potentially any mechanism or structure that can communicate data captured by the sensor components 102 and communicate that information to the provider 92, the patient 90, and/or other devices. In many instances, the communication component 108 will include some type of visual display such as a display screen 147. The communication component 108 may also include audio or even tactile capabilities.

[0119] One common category of communication component 108 is a controller 146. A controller 146 provides two way communications with the apparatus 100, meaning that the controller 146 can both send and receive information from the apparatus 100.

[0120] Some embodiments of the apparatus 100 can involve communication components 108 specially dedicated to providing the functionality of the apparatus 100. For example, a controller 146 can be permanently attached to a sensor strip 142 and serve no purpose outside of the functionality of the apparatus 100. In other embodiments, the apparatus 100 can utilize a general purpose computer 126, a laptop computer, a tablet computer 137, a smart phone 135, or some other non-dedicated device to provide the functionality of the communication component 108.

[0121] In the example of the sensor strip 142 embodiment of the apparatus 100 illustrated in FIG. 5a, the display component 108 is a dedicated controller 146 that includes the ability to not only display information, but to also configure the display of information as well as provide instructions to the sensor components 102 and the apparatus 100 generally.

[0122] F. User Controls

[0123] A user control 114 is either a physical or virtual mechanism by which a user such as a provider 92 or patient 90 can provide an instruction 120 to the apparatus 100. For example, a user control 114 can be used to define the criteria for triggering an alert 122, changing a display format 115, or some other action. In some embodiments, user controls 114 are found in an interfacing device, such as a smart phone 135, tablet computer 137, laptop computer, desktop computer, etc. Examples of user controls 114 include but are not limited to buttons 148, knobs, dials, display screens 147 that are touch screens, keyboards, joysticks, voice recognition technology, light pens, mice, and other commonly known information technology devices for human-machine interactions.

[0124] User controls 114 can impact both the inputs and outputs of the apparatus 100.

[0125] G. Display Formats

[0126] Returning to FIG. 2, different embodiments of the apparatus 100 have the ability to provide different capacities with respect to display formats 115. In some embodiments, the display formats 115 are fixed, and are not subject to configuration by any user. In other embodiments, a user such as a provider 92 or even a patient 90 can use a user control 114 to configure the display formats 115 used by the communication component 108. FIGS. 1f and 1g are examples of display formats 115 that involve graphs of gradients 132.

[0127] H. Cardiac Performance Heuristics

[0128] A cardiac performance heuristic 116 is a predefined process (that is subject to dynamic configuration in some embodiments) that can be created, stored, and automatically invoked in response to a set of triggering criteria. The heuristic 116 can be designed to identify certain follow-up actions in response to certain situations. For example, an alert 122 to a provider 92, a patient 90, or even the family member of a patient 90 can be automatically sent out when triggered by certain sensor measurements and/or other relevant conditions.

[0129] As illustrated in FIG. 1e, it is the cardiac performance heuristic 116 that determines what are the inputs and outputs of the apparatus 100.

[0130] I. User Instructions

[0131] A user instruction 120 is a means by which a user of the apparatus 100 can influence the functionality of the apparatus 100. Different embodiments of the apparatus 100 can possess a different range of configurable options, with some embodiments providing absolutely no capacity to receive user instructions 120. User instructions 120 can impact the functionality of the apparatus 100 in both substantive as well as presentation-related ways.

[0132] J. Alerts

[0133] An alert 122 is a communication generated by the apparatus 100 to convey information. The different recipients of a particular alert 122 can be determined by the applicable instruction 120 setting up the alert 122. Alerts 122 can be transmitted in the immediate physical presence of the apparatus 100, as well as via e-mail, text message, automated phone calls, social media, etc. In different embodiments of the apparatus 100, different individuals can be authorized to

define alerts 122. Security rules can prevent undesirable occurrences, such as for example preventing the overriding of a doctor-defined alert by a member of the patient's family.

[0134] K. External IT Systems

[0135] Any information technology system external to the apparatus 100 is a potential partner of the apparatus 100 with respect to information sharing. Data from external IT systems 112 can be used to improve the derivation of the cardiac performance indicator 89. For example, external IT systems 112 can include patient-specific medical information such as age, medical history, etc. that can impact how sensor readings 87 are interpreted. In addition to providing data inputs to the apparatus 100, external IT systems 112 can also receive inputs from the apparatus 100. For example sensor readings 87 and cardiac performance indicators 89 can be automatically added to a patient's medical records. Information relating to a patient's cardiac performance can impact external devices that may benefit from that knowledge.

[0136] The apparatus 100 can be implemented to support comprehensive data integration by external IT systems 112 that are both broad and comprehensive in scope.

[0137] L. Controller Connector and General Purpose Computers

[0138] A controller connector 124 can be a device physically separate from the other components of the apparatus 100 or it can be integrated into other components, such as a sensor strip. A controller connector 124 allows for the apparatus 100 to interact with general purpose computers 126 such as smart phones 135, tablets 137, laptop computers, and other types of computers to allow users to both receive and submit information to the apparatus 100. This is beneficial for a wide variety of reasons. Specially dedicated interface devices can constitute a needless expense, and many users are more familiar with the user interfaces on their general purpose computer 126. A controller connector 124 provides for using general purpose devices to support the functionality of the apparatus 100. The keyboards, display screens 147, speakers, buttons 148, and other capabilities of the general purpose computer 126 can become temporary components of the apparatus 100. FIGS. 5b and 5c illustrate different examples of such temporary integration.

[0139] M. Connections

[0140] A connection 149 is virtually any mechanism by which information can be exchanged between components in the apparatus 100, or from the apparatus 100 to the outside world. The apparatus 100 can incorporate both wired connections 144 as well as wireless connections 145. In different contexts, different design choices can be honored while implementing the apparatus 100.

#### IV. DETAILED DESCRIPTION OF SENSORS

[0141] Sensor components 102 are the primary component for the apparatus 100 for the gathering of information used by the apparatus 100 to generate an assessment of a patient's cardiac performance (i.e. cardiac performance indicator 89).

[0142] A. Variations of Sensor Components

[0143] FIG. 3a is a hierarchy diagram illustrating an example of different categories of sensor components 102 that can be included in different embodiments of the apparatus 100. FIG. 3a illustrates different types of sensor components 102 based on the type of information captured by the sensor component 102. As illustrated in FIG. 3a, sensor components 102 can utilize oxygen saturation sensors 136, electricity conductivity sensors 138, pH sensors 139, and tem-

perature sensors 140. Other types of non-invasive sensors that can capture meaningful information when positioned on the skin of the patient 90 can be used as sensor components 102 for the apparatus.

[0144] Sensor components 102 can also vary widely in terms of their structural configuration. They can also use different techniques and components for being securely positioned on the patient 90. Some sensor components 102 can be integrated with other components of the apparatus 100 such as processor components 110 and communication components 108, as well as the specific connections 149 (whether wired 144 or wireless 145) that are used.

[0145] B. Example of Sensor Component in a Subassembly

[0146] FIG. 3*b* is a side view diagram illustrating an example of a sensor component and some accompany components that can provide for securing the sensor component on a patient location. The sensor component 102 is mounted to a circuit board 163. The circuit board 163 may include its own communication component 108 or even its own processor component 110. The circuit board 163 and attached sensor component 102 are sandwiched between layers of foam 160. Adhesive layers 161 are disbursed at various locations within the subassembly to keep the various components integral to each other. A peel away layer 162 is positioned at the bottom of the subassembly, providing users with the ability to remove the peel away layer 162, exposing the lowest adhesive layer 161 to come into contact with the skin of the patient 90. This provides for the securing of the sensor component 102 with respect to a particular location 88 on the patient 90.

[0147] Different embodiments of the sensor component 102 can involve different subassembly configurations. Sensor components 102 can be physically attached to each other in some embodiments, while using wired connections 144 in other embodiments. In some embodiments, sensor components 102 will each possess their own means for being securely positioned on the patient 90, while in other embodiments such functionality will reside in a strip 142 or some other form of sensor connector component 104.

[0148] C. Sensor Connector Components

[0149] FIG. 3*c* is a block diagram illustrating an example of a sensor strip 142 that includes 11 securely positioned sensor components 102 in 11 relative positions 133. In many embodiments of the apparatus 100, there will be a relatively high number of sensor components 102. In such instances, having some physical connection mechanism (a sensor connector component 104 such as a sensor strip 142) is highly desirable. It is far easier to grab a single strip 142 by the hand than it is to grab 20 or 30 sensor components 102 that are not attached to anything else. Moreover, the sensor strip 142 also has the advantage of securing each sensor component 102 in a relative position 133 with respect to the other sensor components 102 on the strip 142.

[0150] By having strip 142 securely position multiple sensor components 102 into a single file sequence of sensor components 102, the strip 142 of FIG. 3*c* is both easier to handle, and can readily generate output such as the gradients 132 displayed in FIGS. 1*f* and 1*g*.

#### V. CARDIAC PERFORMANCE HEURISTICS AND INDICATORS

[0151] At the heart of the apparatus 100, is the capability to generate a cardiac performance indicator 89.

[0152] A. Inputs—Different Heuristics Utilize Different Factors

[0153] FIG. 1*e* is an input-output diagram illustrating an example of the different inputs and outputs that can be

involved in the functionality of the apparatus 100. Different embodiments of the apparatus 100 can also give different weight to different inputs. For example, a user instruction 120 from a provider 92 or medical history information from an external IT system 112 may suggest that a particular patient 90 is particularly vulnerable to cardiovascular problems, and as such, the cardiac performance indicators 89 can be correspondingly adjusted with alerts 122 being triggered in that instance when they would not be triggered for other patients 90 in otherwise identical circumstances.

[0154] The apparatus 100 can also utilize some inputs to counteract potential measurement errors with respect to other inputs. By way of example, in the context of temperature sensors 140 it may be desirable for the sensors 140 to also capture ambient temperature measurements 141 to factor in for erroneous sensor readings 87 resulting from differences in insulation for different sensors 140. The upper part of the strip 142 can be covered so as to form an insulation barrier over the sensor 140.

[0155] Further down the strip 142 may not be covered and may not have an insulation barrier. The apparatus 100 may measure a gradient 132 along the strip due to the different ambient conditions. This could possibly be a false positive reading. If the sensor 140 can measure both the skin temperature reading 87 and a related ambient reading 141, then the processor component 110 of the apparatus 100 can normalize the reading 78, or use a correction factor when utilizing the reading. Thus differences in the physical configuration of the sensors 140 can merit differences in the treatment of input variables.

[0156] Given the number of potential input parameters for the cardiac performance heuristics 116, it is not possible to graphically illustrate all of the combinations or to use text to illustrate how a difference with respect to a single input can selectively impact the output of the apparatus 100.

[0157] B. Data—Different Levels of Data and Analysis

[0158] FIG. 4 is a data diagram illustrating the relationships between a data set 97, the sensor readings 87 that can make up a data set 97, and some of the attributes that can relate to a sensor reading 87 such as time 130, frequency 131, and relative position 133. The apparatus 100 and the cardiac performance heuristics 116 that support the functionality of creating cardiac performance indicators 89 can be configured and even customized in a wide variety of different ways.

[0159] Different embodiments of the cardiac performance heuristics 116 can evaluate and compare data at different levels and in different groupings. A data set 97 can include potentially multiple sensor readings 87 from multiple sensor components 102. Comparative analysis is a highly useful tool in looking for evidence of poor cardiac performance. See FIG. 1*g*. Returning to FIG. 4, a data set 97 can correlate to a gradient 132. Composite data sets 132 can include more than one gradient 132. A single gradient 132 can include multiple sensor readings 87. A single sensor reading 87 can be associated with a specific moment in time 130, a specific frequency 131, and a specific relative position 133.

[0160] Just as the cardiac performance heuristic 116 can be implemented in a wide variety of different ways to give different weights to different inputs, the heuristic 116 can also be implemented to operate at different levels of data. Some embodiments of the heuristic can factor in data from multiple data sets 97 while other embodiments can focus exclusively on data from a single apparatus 100 used at a single moment in time 130.

**[0161]** C. Outputs—Cardiac Performance in a Human Being

**[0162]** The human body is a collection of organ systems working together to perform the tasks and meet the needs of the body. Most organ systems work on “as needed” basis and have a less active or dormant state when not needed. Even organs such as the brain and heart which are never truly dormant vary from levels of high activity to levels of substantially lower activity. All organ systems require a blood supply. Blood provides oxygen, nutrients and enzymes. It also carries away cellular metabolic waste products.

**[0163]** An adult human body has approximately five liters of blood. Interestingly, this volume is many times less than the volume the vascular system. This is because while some organs are in a high activity state, other organs are in a less active or dormant state. Therefore, the body continuously directs blood flow to organs that need it and reduces blood flow to inactive organs because there is not enough blood volume to supply all organ systems with maximum blood flow at the same time. For example, during exercise or physical activity the skeletal muscular system requires higher amounts of blood. Conversely, during rest or sleep blood supply to skeletal muscles is reduced because they have less blood supply demand.

**[0164]** Blood flow is managed by the vascular system. The arteries and veins of the vascular system can expand or contract, which is called vasodilation or vasoconstriction, respectively. Vasodilation and vasoconstriction are key components for managing blood flow. At the center of the vascular system is a heart that is responsible for pumping blood throughout the vascular system.

**[0165]** Arteries will vasodilate to allow more blood flow to an organ. They will vasoconstrict to reduce blood flow. Systemic vascular resistance (SVR) is a term used to describe the level of vasodilation or vasoconstriction. SVR is a concept that can be expressed mathematically as a numerical value, a systemic vascular resistance value **93**. Vasodilation is a level of lower systemic vascular resistance. Vasoconstriction is a higher level.

Vasodilation=↓decreased Systemic Vascular Resistance

Vasoconstriction=↑increased Systemic Vascular Resistance

**[0166]** The brain, heart, lungs, liver and kidney are vital organs. Their performance is essential for life, hence their designation as vital. Maintaining blood supply to these organs, even small amounts of blood, is extremely important. If the balance of all organ systems is disrupted for any reason, the body will work toward supplying at least the minimum amount of blood supply to the vital organs. This balance can be changed by many causes.

**[0167]** If a body experiences certain types of trauma or if it is in an aged or diseased state, the cardiovascular organ system could be hindered which changes the balance of all organ systems. If there is trauma resulting in significant blood loss, this could adversely affect the cardiovascular system. Age diminishes all organ systems, including the cardiovascular system. Certain types of diseases such as coronary artery disease or cardiomyopathy affect the heart, which affects the cardiovascular system. Performance of the cardiovascular system is measured by cardiac output. Trauma, age and disease can cause reduced cardiac output. Reduced cardiac output means less blood supply to all organs, including the vital

organs. A natural physiologic response to reduced blood supply is to increase systemic vascular resistance to non-vital organs in order to preserve blood supply for vital organs.

**[0168]** The relationship between a cardiac output estimate **95** and a systemic vascular resistance value is shown in the equation below.

$$\text{Cardiac Output} = \text{Systemic Vascular Resistance} \times \text{Mean Arterial Pressure}$$

**[0169]** Mean arterial pressure is directly and easily measured using a blood pressure cuff. Cardiac output and systemic vascular resistance are not easily measured. Cardiac output can be directly measured by inserting a Swan-Ganz catheter into the pulmonary artery and making a thermal dilution measurement. This provides accurate real-time measurement of cardiac output, which is very valuable. The Swan-Ganz catheter must be indwelling, which means it must remain inserted in the pulmonary artery, to provide continuous measurement. Indwelling catheters can be difficult to maintain. They are susceptible to infection. The decision to use a Swan-Ganz catheter for continuous monitoring of cardiac output must be based on the risk associated with indwelling catheters.

**[0170]** Providers **92** treating patients with extreme trauma or severe disease states will monitor vital signs. It is very desirable to know the cardiac output estimate **95**. This information helps guide and assess treatment of the patient **90**. A device that could non-invasively monitor cardiac output accurately and continuously would be valuable. The apparatus **100** is such a device.

**[0171]** Reduced cardiac output leads to increased systemic vascular resistance for non-vital organs, which means less blood supply to these organs. Blood supply will be reduced to the extremities, meaning the arms and legs. If cardiac output is reduced by only a small amount, blood supply will only be reduced to the far ends of the extremities, which are the hands and feet. If reduction is more severe, blood supply will be reduced to more portions of the extremities.

**[0172]** Reduced blood supply to the extremities will result in decreased dermal temperature, which is skin temperature. Depending on the level of cardiac output, a temperature gradient may develop from the top-to-bottom of the extremity. For example, the upper and mid portion of the thigh may be at or near normal temperature, but the calf and foot may be colder. Therefore, monitoring skin temperature may be a valuable way to non-invasively monitor cardiac output.

**[0173]** Blood supplies many things to organs. Heat is one example of what blood can supply. Hence, skin temperature can be a non-invasive monitor of cardiac performance. Oxygen is present in blood. Dermal oxygen saturation levels may also serve as a way to monitor cardiac output. If an O<sub>2</sub> saturation gradient is measured along the length of an extremity, it may indicate changes in cardiac output. Other blood or dermal parameters may also be monitored to indicate cardiac performance, such as pH levels or electrical properties like conductivity or resistance.

## VI. VARIATIONS IN COMMUNICATION COMPONENTS

**[0174]** As discussed above, the communication component **108** is the means by which information such as a cardiac performance indicator **89** is communicated to the provider **92**. A controller **146** is a communication component **108** that is capable of both sending information from a user as well as

transmitting information to the user. Different embodiments of the apparatus 100 can involve communication components that are specially dedicated and even permanently attached to the sensor components 102. Other embodiments allow users to temporarily integrate general purpose computers 126 to provide the interface between user and apparatus 100.

[0175] A. Permanently Attached and Dedicated Controller  
 [0176] FIG. 5a is diagram illustrating an example of an apparatus 100 that has a fully dedicated special purpose controller 146. The controller 146 is not configured to be removed from the sensor strip 142 by users. The apparatus 100 has a sensor strip 142 of eight sensor components 102. The strip 142 is attached to a controller 146 that includes a display screen 147 and several buttons 148. The buttons 148 coupled with a user menu on the display screen 147 can be used to select display formats 115, submit user instructions 120, and provide other types of inputs to the apparatus 100 as discussed above.

[0177] B. Wired Controller Connector

[0178] FIG. 5b is a diagram illustrating an example of an apparatus 100 that uses a wired controller connector 124 (such as a USB cord, a network cable, or some similar type of wired connector 124 to connect a general purpose computer 126 to the sensor components 102 of the apparatus 100. Instead of using a fully dedicated and permanently attached controller 146, FIG. 5b illustrates an example of where a user can utilize a general purpose computer that they already have to interact with the sensors components 102.

[0179] C. Wireless Controller Connector

[0180] FIG. 5c is a diagram illustrating an example of an apparatus 100 with sensor components 102 that can interact with a general purpose computer 126 without the inclusion of a controller connector 124. In FIG. 5c, the sensor components 102 themselves can include their own communication capabilities that provide for direct wireless communication with a general purpose computer 126.

## VII. TEMPERATURE-BASED EMBODIMENTS OF THE APPARATUS

[0181] Although the apparatus 100 can be implemented in a wide variety of different embodiments, the conception of the apparatus 100 was originally inspired to include the use of temperature sensors 140.

[0182] A. Process-Flow Views

[0183] 1. Single Gradient Example

[0184] FIG. 6a is a flow chart diagram illustrating an example of a process by which a systemic vascular resistance value 93 is calculated using sensor readings 87 from a temperature sensor 140.

[0185] At 210, the sensor strip 142 is positioned on an appendage 190 such as an arm or leg.

[0186] At 212, a data set 97 of sensor readings 87 is captured.

[0187] At 214, the captured sensor readings 87 are displayed. This display format 115 can be similar to the format illustrated in FIGS. 1f and 1g.

[0188] At 216, the systemic vascular resistance value 95 is calculated using the processor component 110. The value 95 can be displayed, compared to a predefined threshold value 134 for the purpose of selecting triggering an alert 122, or put to use in one or more of the ways discussed above.

[0189] 2. Two Gradient Example

[0190] FIG. 6b is a flow chart diagram illustrating an example of two gradients 132 being compared/contrasted with each other to selectively derive the applicable cardiac performance indicator 89.

[0191] This process continues with the second gradient 132 after steps 210 through 216 discussed above are performed.

[0192] At 220, a sensor strip 142 is positioned on a second appendage 190. This can be the same strip 142 as in step 210 but a different moment of time 130 or it can be a different strip 142 at the same moment of time 130 or at a different moment of time 130.

[0193] At 222, a second data set 97 of sensor readings 87 are captured.

[0194] At 224, the gradient 132 corresponding to the second data set 97 can be displayed. In some embodiments, it can be helpful to illustrated both gradients 132 simultaneously for comparison purposes.

[0195] At 226, the gradients 132 can be compared both visually as well as analytically. As discussed above, the cardiac performance heuristic 116 can be specifically tailored to perform gradient 132 to gradient 132 comparisons for the purposes of generating a cardiac performance indicator 89.

[0196] B. Environmental Views/Operating Configurations

[0197] The process flows illustrated in FIGS. 6a and 6b above can be performed in a wide variety of different configurations, including but not limited to the configurations illustrated in FIGS. 7a and 7b.

[0198] 1. Side View

[0199] FIG. 7a is a side view environmental diagram illustrating an example of the apparatus 100 in the context of temperature sensors 140 being positioned on a leg 190 of the patient 90. The temperature sensors 140 are embedded in a sensor strip 142 that is coated with an adhesive layer 161 to facilitate being position on the skin of the patient 90. The controller 146 is attached to the sensor strip 142 through a cord 144 that provides both power and communications to the sensor strip 142.

[0200] 2. Rear View

[0201] FIG. 7b is an environmental diagram illustrating an example of the apparatus 100 in the context of temperature sensors 140 being positioned on a leg 190 of the patient 90. FIG. 7b is a rear view of the illustration in FIG. 7a.

[0202] C. Description of Components—Temperature Sensor Apparatus

[0203] 1. Temperature Sensors

[0204] An array of temperature-based sensors 140 (temperature sensors 140) are used in the illustrated sensor-strip embodiment of the apparatus 100. The number of sensors 140 can vary widely. In the context of leg-based applications, it can be desirable to have between about 5-15 sensors for the thigh area, between about 10-20 sensors for the back of the knee, and between about 5-10 sensors for the calf area.

[0205] 2. Sensor Strip

[0206] The array of sensors 140 is housed in a sensor strip 142 that can be securely positioned onto the leg or arm of a patient 90. The sensor strip 142 can be designed for positioning from the mid-thigh to mid-calf area, although alternative embodiments can be designed to extend all the way down the backside of the leg.

[0207] 3. Electrical Cord

[0208] The wired connection 144 illustrated in FIGS. 7a and 7b is an electrical cord. Virtually any wired connection 144 or wireless connection 145 can serve as the connection 149 between components 149. However, the use of wired connections 144 helps to keep the apparatus 100 integrated as a single device which can make it easier to deploy as well as store.

**[0209]** 4. Controller

**[0210]** A controller **146** is a single device houses the communication component **108** (in the form of a screen **147**) and the processor component **110**. The controller **146** can provide various user controls **114** (such as a physical button **148** in the housing of the control unit **146**) to allow users to change display formats **115**. In some embodiments, the control unit **145** can be used to create heuristics **118**, submit instructions **120**, create automatically invoked alerts **122**, and to output data to external IT systems **112**.

**[0211]** As discussed above, some embodiments of the apparatus **100** can support a general purpose computer device such as a smart phone **135**, tablet computer **137**, laptop computer, etc. serving as the controller **146**.

**[0212]** D. Detection of SVR

**[0213]** A temperature-based sensor-strip embodiment of the apparatus **100** is designed to detect systemic vascular resistance values **95** in the extremities of the patient **90**.

**[0214]** The apparatus **100** will measure the skin temperature of a patient's leg. The apparatus **100** can have the ability to measure temperature at more than one location **88** at the same moment in time **130**—with measurements be taken either continuously or periodically over a period of time. The apparatus **100** can continuously measure temperature at all locations and immediately provide measurement information to a processor component **110** that is part of the apparatus **100** (typically housed within the controller **146**) and/or to external systems/applications involved in the monitoring of the patient's medical status and in the treating of the patient **90**. In many embodiments, a screen **147** on the controller **146** will display all temperature measurements immediately and continuously. Displayed temperature measurements may be in the form of a data plot, with skin location along the X-axis and temperature measurement along the Y-axis. Other data formats **115** can be selected using the buttons **148** on the controller **146** or through other user controls **114**. The apparatus **100** can also record measurement information so the information can be reviewed later. Recorded information will include date, time of day and possibly time since recording started. The apparatus **100** may have the capabilities to trigger alerts **122** to indicate particular information, such as temperatures above or below certain limits, variations of temperature between measurement locations or variations of temperature over the time.

**[0215]** The apparatus **100** can include: (1) multiple temperature sensors **140**; (2) encompassed in a sensor strip **142**; (3) that is connected to controller **146**; (4) by a cord **144**. The strip **142** of sensors **140** can be attached to the backside (posterior) of a patient's leg. The strip **142** can be long enough to extend from about mid-thigh to mid-calf. The strip **142** can be attached to the patient **90** using adhesive, similar to the way in which a bandage is attached to the skin. Other attachment means are possible. In a preferred embodiment, the apparatus **100** will attach as conveniently as possible so that only one person is needed to attach the strip **142** to the leg, and so that a patient **90** may be able to attach the strip **142** without outside assistance.

**[0216]** The strip **142** of the apparatus **100** can contain a variable number of temperature sensors **140**, with that range being between about 24 to 36 temperature sensors **140** in many instances. The strip **142** can be designed to stay on the patient **90** for an extended period of time, maybe as long as about 1 or 2 days. It can be as comfortable as possible for the patient **90** and with a low visual profile. The strip **142** can be

designed to insulate it from ambient temperature effects. The strip **142** can be made from biocompatible materials and meet any patient **90** safety needs or skin safety needs. The strip **142** can use a cord **144** (or a wireless network) to connect to a display component **109** such as the controller **146** with a screen **147**. The display instrument will display all the temperature measurement information. The screen **147** can display the information immediately and continuously, or as is otherwise desired through the configuration of the controller **146**. The controller **146** can be a small device, maybe handheld size or notepad size. In some instances, it will be a general purpose computer, such as a smart phone **135**, tablet computer **137**, etc. The controller **146** may lie on the bed next to the patient **90**, or be attached to the hospital bed. The controller **146** may be battery powered or plug into a wall outlet.

**[0217]** Some embodiments of the apparatus **100** can have the ability to transmit measurement information to other devices, systems, and applications, such as general purpose computers **126** (including tablet computers **137** and smart phones **135**) or specialized medical systems.

**[0218]** It is envisioned that the apparatus **100** may be used on other locations of the patient than just the leg. For example, the arm of the patient **90** is another likely location for use of the apparatus **100**.

**[0219]** The apparatus **100** can be used to monitor a patient **90** in a wide variety of different contexts. Cardiac output **95** is an important physiologic parameter that is monitored in some patients **90**. It is desired to know as quickly as possible if cardiac output starts to decrease. Decreased output can be a serious problem that can lead to cardiogenic shock, which requires immediate medical attention to resuscitate and maintain a patient's life. A physiologic response to decreased cardiac output is to protect vital organs by changing systemic vascular resistance. Vascular resistance of the skin is increased in order to reduce blood flow to the skin. Reduced blood flow to the skin means more blood supply is available to vital organs. Reduced blood flow to the skin also means reduced skin temperature. Therefore, the apparatus **100** can monitor cardiac output by detecting skin temperature changes which are a symptom of changes to systemic vascular resistance. This can be an early warning sign of possible cardiogenic shock and the need for immediate medical attention.

**[0220]** The apparatus **100** can provide this warning by displaying changes in leg skin temperature. Reduced skin blood flow will start at the farthest locations of the extremities, the fingers and the toes. If necessary, reduced flow will continue to progress up the extremities; the arms and legs. The device will be able to display changes in skin temperature. For example, the screen **148** would show normal skin temperature in the thigh region and lower skin temperature in the calf region. If the patient's condition worsens, the screen **148** may show lower than normal temperatures along the entire leg.

**[0221]** The device is envisioned to be used in many different places. It can be used in an emergency room (ER), intensive care unit (ICU), critical care unit (CCU), surgical recovery, elsewhere in a hospital setting, ambulances, nursing care facilities and patient's homes.

**[0222]** It may be possible to monitor other skin parameters that are affected by cardiac output. For example, it is envisioned that this device could measure electrical resistance, pH, chemical or light changes to skin. It may also be possible to implement the apparatus **100** outside the context of skin sensors.

**[0223]** E. Data Display Formats

**[0224]** FIG. 1f is an example of a temperature chart that could be generated by application of a sensor-strip embodiment of the apparatus 100 used on the leg of a relatively healthy patient 90.

**[0225]** The display component 108 of the apparatus 100 can display the temperature measurement. The vertical axis is temperature. The horizontal axis is the relative position 133 of the sensor 140. The first sensor may be the sensor at the patient's mid-thigh. The last sensor may be the sensor at the patient's mid-calf, or alternately their toes. FIG. 1f shows all sensors measuring the same temperature. This would happen if there is no temperature gradient between sensors. This would tell the doctor that the leg skin temperature is uniform from thigh to calf, or thigh to toes.

**[0226]** FIG. 1g is an example of a temperature chart that could be generated by the application of a sensor-strip embodiment of the apparatus used on the leg of a patient with circulatory problems.

**[0227]** FIG. 1g shows a temperature gradient between the temperature sensors 140. The sensors 140 in the thigh area, sensors 1-12, all display the same temperature of 37° C. The sensors 140 in the middle area across the back of the knee, sensors 13-27, display a consistent decrease in temperature.

The last sensors 140 in the calf area, sensors 28-36, show a consistent low temperature of 21° C. The gradient shown above results from the leg skin being at different temperatures. This may result from the patient's body responding to a decrease in cardiac output. The body responds by increasing systemic vascular resistance (SVR). Increased SVR means less blood flow to peripheral areas, such as arms and legs. Less blood flow in arms or legs can be detected by skin temperature gradient.

**[0228]** Different embodiments of the apparatus 100 can trigger different alerts 122 based on the magnitude of the temperature gradient indicated in the display, changes in temperature over time, or a temperature measurement falling outside a predefined safe range. Such settings can also be customized to factor in other attributes related to the patient 90. In some embodiments, providers 92 can customize the triggering criteria for an alert 122 to include data supplied to the apparatus 100 that does not originate from the sensors 140 within the apparatus 100.

## VIII. INDEX OF ELEMENTS

**[0229]** Table 1 below provides an index of element names and element numbers.

TABLE 1

Element Number	Element Name	Description
85	Patient Attribute	Potentially any attribute of the patient 90 that can be relevant for the purposes of assessing the cardiac performance of a patient 90 and that can be captured in the form of a sensor reading 87 by a sensor component 102. Examples of potentially relevant patient attributes 85 can include skin temperature, pH level, electrical conductivity, oxygen saturation and other attributes that can be either directly or indirectly measured.
87	Sensor Reading	A measurement, determination, observation, assessment, or potentially other forms of output by a sensor component 102 in relation to a patient attribute 85. Examples of sensor readings 87 can include temperature, pH level, electrical conductivity, oxygen saturation and other data relating to one or more patient attributes 85. A sensor reading 87 can include within it data relating to the sensor component 102 that captured the sensor reading 87, such as a relative position 133 of the sensor component 102 with respect to other sensor components 102, the location 88 of the sensor component 102 with respect to the patient 90, the identity of the patient 90, and other potential patient attributes 85.
88	Location	A position on the patient 90 on which a sensor component 102 is placed and a sensor reading 87 is captured. In many embodiments of the apparatus 100, locations 88 are on the skin of the patient 90.
89	Cardiac Performance Indicator	An assessment generated by the apparatus 100 with respect to the cardiac performance of the patient 90. Examples of potential cardiac performance indicators 89 include an arterial perfusion indicator 91, a cardiac output estimate 95 and a systemic vascular resistance value 93.
90	Patient	A living organism, typically a human being.
91	Arterial Perfusion Indicator	An assessment generated by the apparatus 100 that relates to the delivery of blood to a capillary bed in biological tissue. Overperfusion is a condition where too much blood is delivered, and underperfusion is a condition where too little blood is delivered. An arterial perfusion indicator 91 is an example of a type of cardiac performance indicator 89.
92	Provider	A doctor, nurse, nurse practitioner, lab technician, physician assistant, paramedic, or other person involved in evaluating the health of the patient 90.
93	Systemic Vascular Resistance Value	A metric representing resistance and/or blockage to the flow of blood in a patient 90. System vascular resistance value 93 is an example of a potential cardiac performance indicator 89.

TABLE 1-continued

Element Number	Element Name	Description
95	Cardiac Output Estimate	A metric representing the aggregate output of the heart and cardiovascular system of the patient 90. This is an example of a potential cardiac performance indicator 89.
97	Data Set	A collection of data. The processor component 110 can compare individual sensor readings 87 to derive a cardiac performance indicator 89. Entire sets 97 of sensor readings 87 can be used to derive a cardiac performance indicator 89.
100	Sensor Apparatus (or simply the Apparatus)	An assembly of components that includes two or more sensor components 102 and a processor component 110. The apparatus 100 provides for using two or more sensor components 102 to capture sensor readings 87 relating to patient attributes 85 and for using a processor component 110 to derive a cardiac performance indicator 89 from those sensor readings 87.
102	Sensor Component (or simply "Sensor")	A device that detects or measures a physical property. Sensor Components 102 can be defined with respect to the phenomenon that is measured/detected or by the mechanisms by which a sensor functions, i.e. electronic, mechanical, electro-mechanical, etc. Examples of different sensor components 102 that can be incorporated into the apparatus 100 include temperature sensors 140, pH sensors 139, electrical connectivity sensors 138 and oxygen saturation sensors 136.
104	Sensor Connector Component	A device or structure that secures two or more sensor components 102 together. An example of a sensor connector component 104 is a strip 142 used to secure the relative positions 133 of a single-file sequence of sensor components 102.
108	Communication Component	A device that communicates the cardiac performance indicator 89, the sensor readings 87, and/or other information to a provider 92 or other user. In many embodiments, the processor component 110 is embedded into the communication component 108.
110	Processor Component	A component or subassembly within the apparatus 100 that includes a computer processor that performs the processing logic of one or more cardiac performance heuristics 116 to generate a cardiac performance indicator 89.
112	External IT System	An information technology system 112 used to treat the patient 90 that is outside the scope of the apparatus 100. The sensor readings 87 of the apparatus 100 can be integrated into broader and/or comprehensive systems being used to treat the patient 90. The Exterior System 112 can add to the factors that influence the creation of the cardiac performance indicator 89 derived for a particular patient 90.
114	User Controls	A physical or virtual mechanism by which a user of the apparatus 100 can impact the function of the apparatus 100. User controls 114 allow the apparatus 100 to receive inputs from users such as providers 92.
115	Display Format	An arrangement of information. The apparatus 100 can provide for providing users with access to data in a variety of different display formats 115. FIGS. 1f and 1g are examples of display formats 115 that may be useful.
116	Cardiac Performance Heuristic	A process by which a cardiac performance indicator 89 is derived from sensor readings 87 and potentially other types of inputs.
120	User Instruction	Operating configuration parameters submitted to the apparatus 100 through one or more user controls 114. A user instruction 120 is submitted to the apparatus 100 through a user control 114.
122	Alerts	A notification generated by the apparatus 100 in conjunction with a cardiac performance indicator 89. By way of example, a cardiac performance indicator 89 can selectively trigger an audio alarm, a text message, an e-mail, an automated phone call, or some other form of notification to a provider 92 or patient 90.
124	Controller Connector	A device that allows the apparatus 100 to interface with general purpose computers 126 such as smart phone 135, tablet computer 137, laptop computer, or other type of general purpose device. Examples of interface devices can be a component connector to a sensor strip 142 with a USB connector for connecting to the general purpose computer device.

TABLE 1-continued

Element Number	Element Name	Description
126	General Purpose Computer	A smart phone, tablet computer, laptop computer, desktop computer, or other form of computer device that provides users with the capability to add applications and to run software not limited to a specific purpose inherent to the device.
130	Moment in Time	A date/time identifier that can be associated with a sensor reading <sup>87</sup> . By way of example, a gradient 132 of sensor readings 87 will often involve sensor measurements captured at the same time but from different locations 88 on the patient 90.
131	Frequency	A rate of occurrence that sensor readings 87 are captured by a sensor component 102.
132	Gradient	A vector of sensor readings 87 and the locations 88 (or in some instances relative positions 133) associated with those sensor readings <sup>87</sup> .
133	Relative Position	A position of a sensor component 102 (and corresponding sensor readings 87) that is defined in respect to the other sensor components 102. For example, in a strip 142 of 10 sensor components 102, sensor #2 would be positioned between sensor #1 and sensor #3. The gradient 132 can be based on relative positions 133 as well as locations 88.
134	Threshold Value	A value that exists for the purposes of comparison with a cardiac performance indicator 89. An alert 122 can be automatically triggered by the processor component 110 when the cardiac performance indicator 89 has some mathematical relationship with respect to the threshold value 134, i.e. less than, less or equal to, greater than, greater than or equal to, etc.
135	Smart Phone	A general purpose computer 126 in the form of a cellular phone.
136	Oxygen Saturation Sensor	A sensor component 102 that measures or estimates the magnitude of oxygen saturation in the blood of a patient 90.
137	Tablet	A general purpose computer 126 in the form of a portable tablet.
138	Electrical Conductivity Sensor	A sensor component 102 that detects and measures the magnitude of electrical conductivity on the skin of the patient 90.
139	pH Sensor	A sensor component 102 that measures the acidity of the skin of the patient 90.
140	Temperature Sensor	A sensor component 102 that measures temperature information.
141	Ambient Readings	A sensor measurement captured with respect to the exterior environment of the patient 90.
142	Sensor Strip	A physical strip that secures the position of two or more sensor components 102.
144	Wired Connection	A connection 149 involving a physical wire to exchange information between components.
145	Wireless Connection	A connection 149 that does not involve the use of a physical wire to exchange information between components. Virtually any form of wireless technology including but not limited to Bluetooth, WiFi, cell phone networks, etc. can be used to provide a wireless connection 145.
146	Controller	A device that provides for outputs from the apparatus 100 to the user. The controller 146 can also in some embodiments be used to convey instructions 120 to the apparatus 100.
147	Screen_(or Display Screen)	A visual display 147 similar to what is used on consumer electronics devices, such as a monitor, smart phone 135, or tablet 137. In some embodiments, the screen 147 is a touch screen that also functions as one or more user controls 114.
148	Button	An example of a type of user control 114. Buttons 148 can be virtual or physical.
149	Connection	A capability to communicate information between two different components, subassemblies, etc.
160	Foam Layer	A layer of insulation used with respect to a component of the apparatus 100.
161	Adhesive Layer	A layer of glue or other similar adhesive used to hold different components of the apparatus 100 together and/or secure the position of the apparatus 100 on the patient 90.
162	Peel Away Layer	A layer positioned on an adhesive layer 161 such that the removal of the peel away layer 162 exposes an adhesive layer 161 that can secure the position of the apparatus 100 on a location 88 of the patient 90.
163	Circuit Board	A board on which electronics can be mounted. In some embodiments, the sensor component 102 and/or processing component 110 are mounted on a circuit board 163.
190	Appendage	A limb of a patient 90, such as an arm or leg.
191	Core Location	A portion of an appendage 190 that is closest to the torso of the patient 90.

TABLE 1-continued

Element Number	Element Name	Description
192	Extremity Location	A portion of an appendage 190 that is the farthest away from the torso of the patient, such as the fingers or toes.

## IX. SCOPE OF THE DISCLOSURE

[0230] The description of the apparatus **100** and various components and subcomponents provided above should be understood to include all novel and non-obvious combination of elements described herein, and claims may be presented in this or a later application to any novel non-obvious combination of these elements. Moreover, the foregoing embodiment is illustrative, and no single feature or element is essential to all possible combinations that may be claimed in this or a later application.

1. An apparatus for detecting a cardiac performance indicator that relates to a patient with a plurality of locations, including a first location and a second location, said apparatus comprising:

a plurality of sensor components positioned at the plurality of locations, said plurality of sensor components providing for the capture of a plurality of sensor readings, said plurality of sensor components including a first sensor component and a second sensor component, said plurality of sensor readings including a first sensor reading and a second sensor reading, wherein said first sensor reading is captured by said first sensor component at the first location, and wherein said second sensor reading is captured by said second sensor component at the second location; and

a processor component that provides for receiving said plurality of sensor readings and selectively identifying the cardiac performance indicator by comparing said sensor readings.

2. The apparatus of claim **1**, wherein said plurality of sensor components includes at least one of: (a) a temperature sensor; (b) a pH sensor; (c) an electrical conductivity sensor; and (d) an oxygen saturation sensor.

3. The apparatus of claim **1**, wherein said plurality of sensor readings are captured at a plurality of moments in time, said plurality of moments in time including a first moment in time and a second moment in time, said plurality of sensor readings further including a third sensor reading and a fourth sensor reading, wherein said first sensor reading is captured at said first moment in time, wherein said second sensor reading is captured at said first moment in time, wherein said third sensor reading is captured at the first location at said second moment in time, and wherein said fourth sensor reading is captured at the second location at said second moment in time.

4. The apparatus of claim **1**, wherein said cardiac performance indicator is an arterial perfusion indicator.

5. The apparatus of claim **1**, wherein said plurality of sensor readings include an ambient reading captured by at least one of said plurality of sensor components, and wherein said cardiac performance indicator is selectively influenced by said ambient reading.

6. The apparatus of claim **1**, said apparatus further comprising a strip, wherein said plurality of sensor components are physically connected to each other in a single-file

sequence by said strip and wherein each sensor component is associated with a relative position.

7. The apparatus of claim **1**, wherein each said sensor reading is associated with a relative position pertaining to said sensor component capturing said sensor reading

8. The apparatus of claim **1**, further comprising a controller.

9. The apparatus of claim **8**, wherein said controller is a general purpose computer.

10. The apparatus of claim **9**, wherein said general purpose computer includes at least one of: (a) a smart phone; and (b) a tablet computer.

11. The apparatus of claim **8**, wherein said controller component includes a display screen and a button.

12. The apparatus of claim **1**, wherein said sensor components are connected to each other by a strip.

13. The apparatus of claim **12**, wherein said strip connects said plurality of sensor components to said processor component.

14. The apparatus of claim **1**, wherein said processor component provides for receiving said plurality of sensor readings from said plurality of sensor components over a wired connection.

15. The apparatus of claim **1**, further comprising:

a plurality of foam layers, said plurality of foam layers including a first foam layer and a second foam layer;

a plurality of adhesive layers, said plurality of adhesive layers including first adhesive layer and a second adhesive layer;

a peel away layer; and

a circuit board;

wherein said sensor component and said processor are mounted on said circuit board;

wherein said circuit board is positioned between said first foam layer and said second foam layer;

wherein said first adhesive layer is positioned between said circuit board and said second foam layer; and

wherein said second adhesive layer is positioned between second foam layer and said peel away layer.

16. The apparatus of claim **1**, further comprising a controller, wherein said controller includes a display screen, a plurality of user controls, said plurality of user controls including a button, and said processor component.

17. The apparatus of claim **16**, wherein said controller provides for receiving a user instruction and transmitting said user instruction to at least one said sensor component, wherein said user instruction pertains to at least one of: (a) a frequency at which said sensor readings are captured; and (b) a threshold value for selectively triggering an alert based by said cardiac performance indicator.

18. A method for detecting a cardiac performance indicator that relates to a patient, comprising:

using a plurality of sensor components positioned at a plurality of locations on the skin of the patient to capture a plurality of sensor readings;

using a processor component to compare said plurality of sensor readings; and

using the processor component to identify the cardiac performance indicator from the comparison of sensor readings.

**19.** A method for detecting a cardiac performance indicator that relates to a patient, comprising:

positioning a sensor strip that includes a plurality of skin temperature sensor components on a first appendage of the patient from a core location to an extremity location; capturing a first set of skin temperature readings pertaining to the first appendage of the patient;

displaying the first set of skin temperature readings as a first gradient; and

calculating a systemic vascular resistance value and a cardiac output estimate using said first gradient;

wherein said cardiac performance indicator is said cardiac output estimate.

**20.** The method of claim **19**, further comprising:

positioning said sensor strip on a second appendage of the patient from a core location to an extremity location;

capturing a second set of skin temperature readings pertaining to the second appendage of the patient;

displaying the second set of skin temperature readings as a second gradient; and

comparing said first gradient to said second gradient;

wherein the identification of said cardiac performance indicator is selectively influenced by the comparing of said first gradient to said second gradient.

\* \* \* \* \*

专利名称(译)	用于评估心脏性能的非侵入式传感器设备和方法		
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摘要(译)

用于评估心脏性能的非侵入式传感器设备和方法。各种不同的传感器组件可以捕获与患者属性相关的传感器读数。然后通过处理器组件比较那些传感器读数以得出与患者相关的心脏性能指标。

