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(12) **United States Patent**
Wekell

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(54) **SYSTEM AND METHOD FOR PATIENT MONITORING**

(71) Applicant: **BODIGUIDE INC.**, Bellevue, WA (US)

(72) Inventor: **William Oren Wekell**, Maple Valley, WA (US)

(73) Assignee: **BODIGUIDE INC.**, Bellevue, WA (US)

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A61B 5/0205 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 5/4878*** (2013.01); ***A61B 5/0002*** (2013.01); ***A61B 5/0004*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC ... A61B 5/4878; A61B 5/0004; A61B 5/0205; A61B 5/1118; A61B 5/4839;
(Continued)

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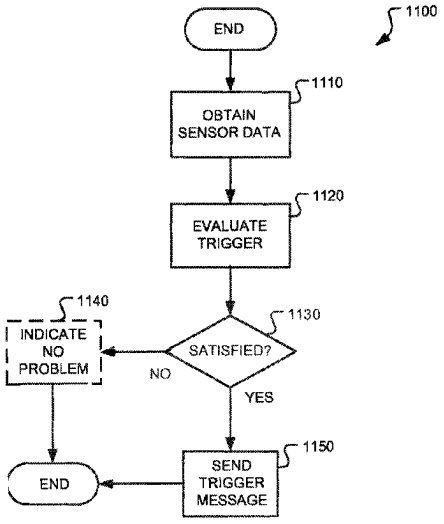
Primary Examiner — Sean P Dougherty
(74) *Attorney, Agent, or Firm* — Conley Rose, P.C.

(57) **ABSTRACT**

Systems and methods of monitoring a patient. Exemplary methods include receiving sensor data associated with the patient from a plurality of sensors of a patient monitoring device and determining whether the sensor data satisfies one or more trigger conditions. For each of the trigger conditions satisfied, one or more messages are sent to at least one of the patient monitoring device and an external computing device for display thereby to at least one of the patient, a caregiver, and a support person. Satisfaction of one or more of the trigger conditions may indicate the patient has edema and/or is trending toward decompensation. The sensor data may have been collected from a heart rate sensor, an oximeter, an accelerometer, and/or a sensor configured to detect a distance around a limb of a patient. In some embodiments, the trigger conditions are provided by the patient, caregiver, and/or support person.

20 Claims, 17 Drawing Sheets



Related U.S. Application Data

continuation of application No. 12/987,985, filed on Jan. 10, 2011, now Pat. No. 8,827,930.

(51) **Int. Cl.**

A61B 5/024	(2006.01)
A61B 5/107	(2006.01)
A61B 5/11	(2006.01)
A61B 5/145	(2006.01)

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

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(58) **Field of Classification Search**

CPC A61B 5/4848; A61B 5/486; A61B 5/7275; A61B 5/7282; A61B 5/024

See application file for complete search history.

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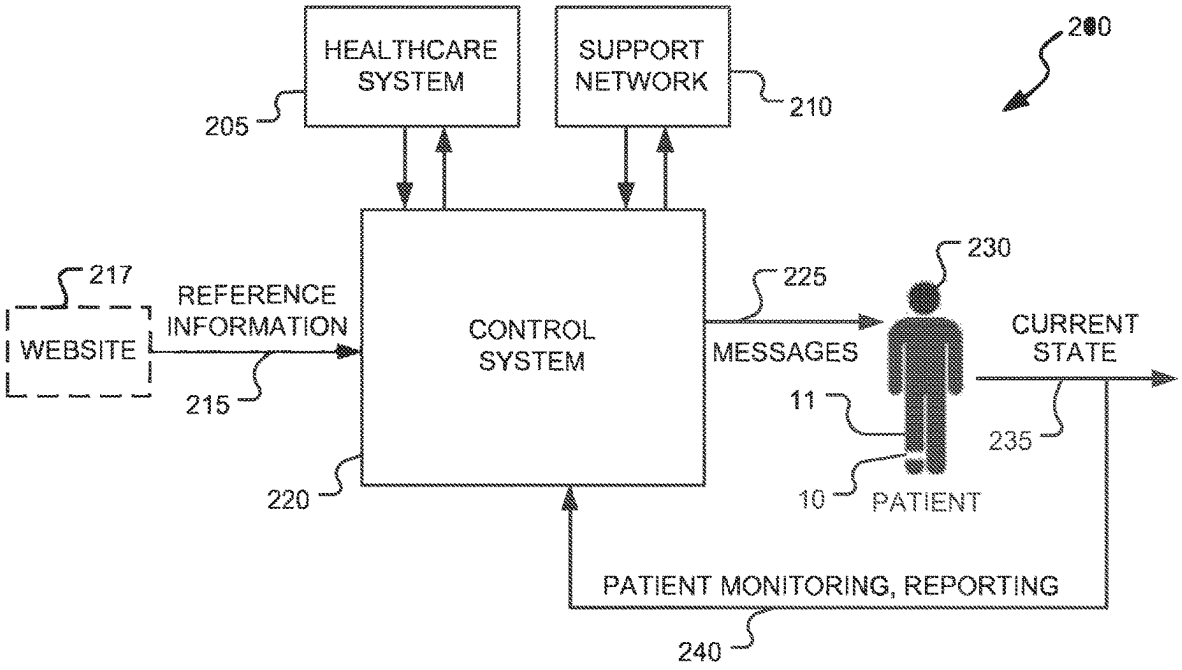
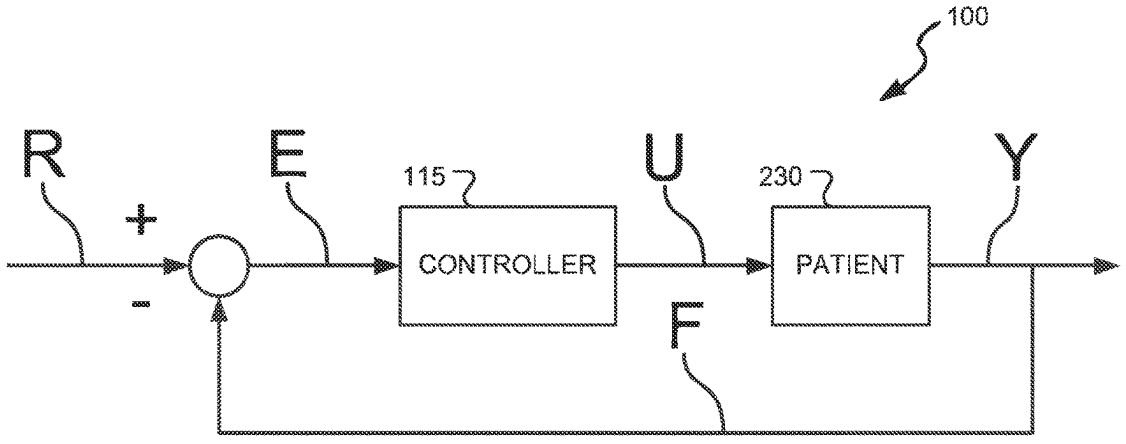


FIGURE 1



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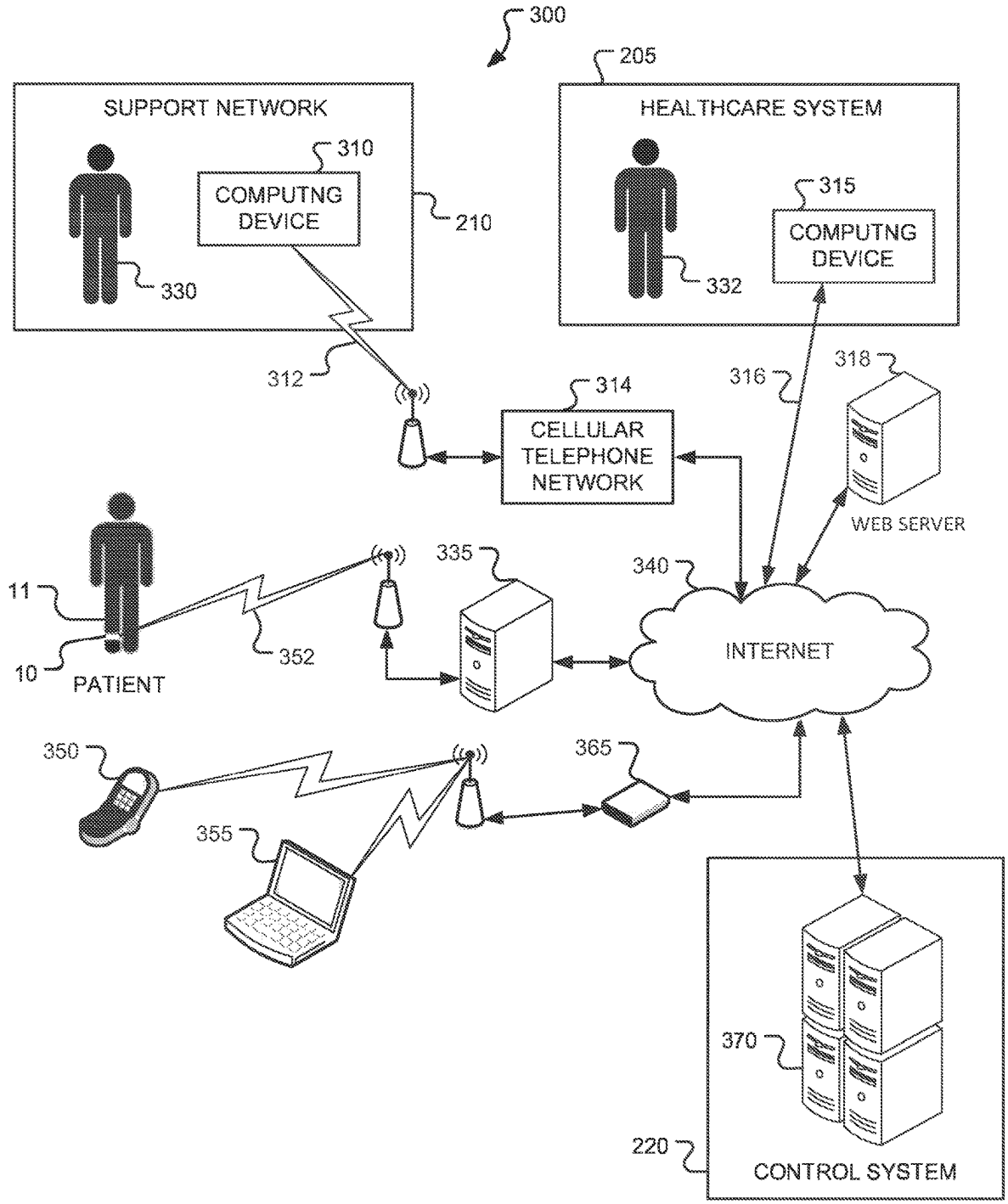
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CELLULAR TELEPHONE NETWORK
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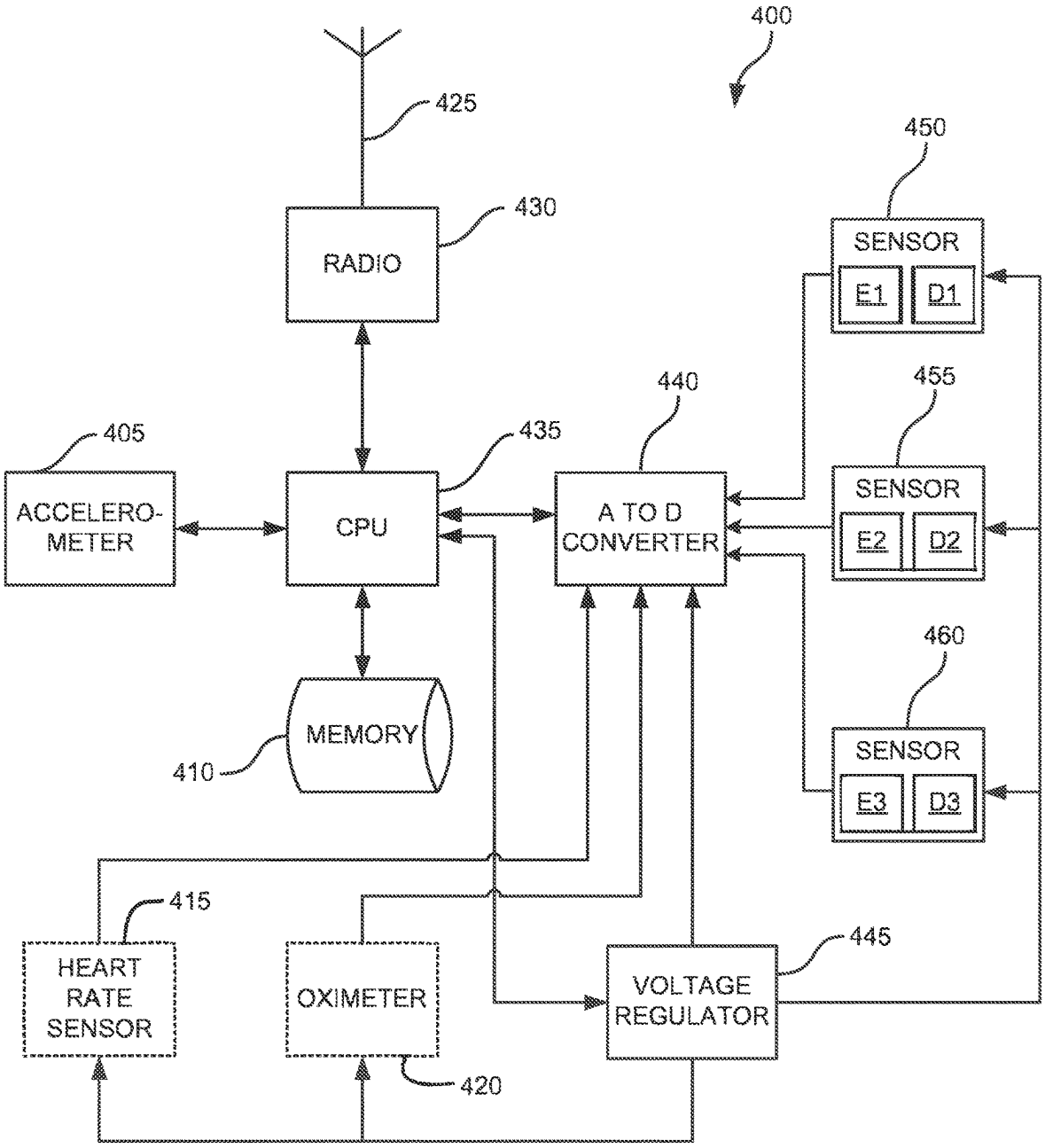
CONTROL SYSTEM

FIGURE 3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SENSOR
E2
D2
460
MEMORY
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VOLTAGE
REGULATOR
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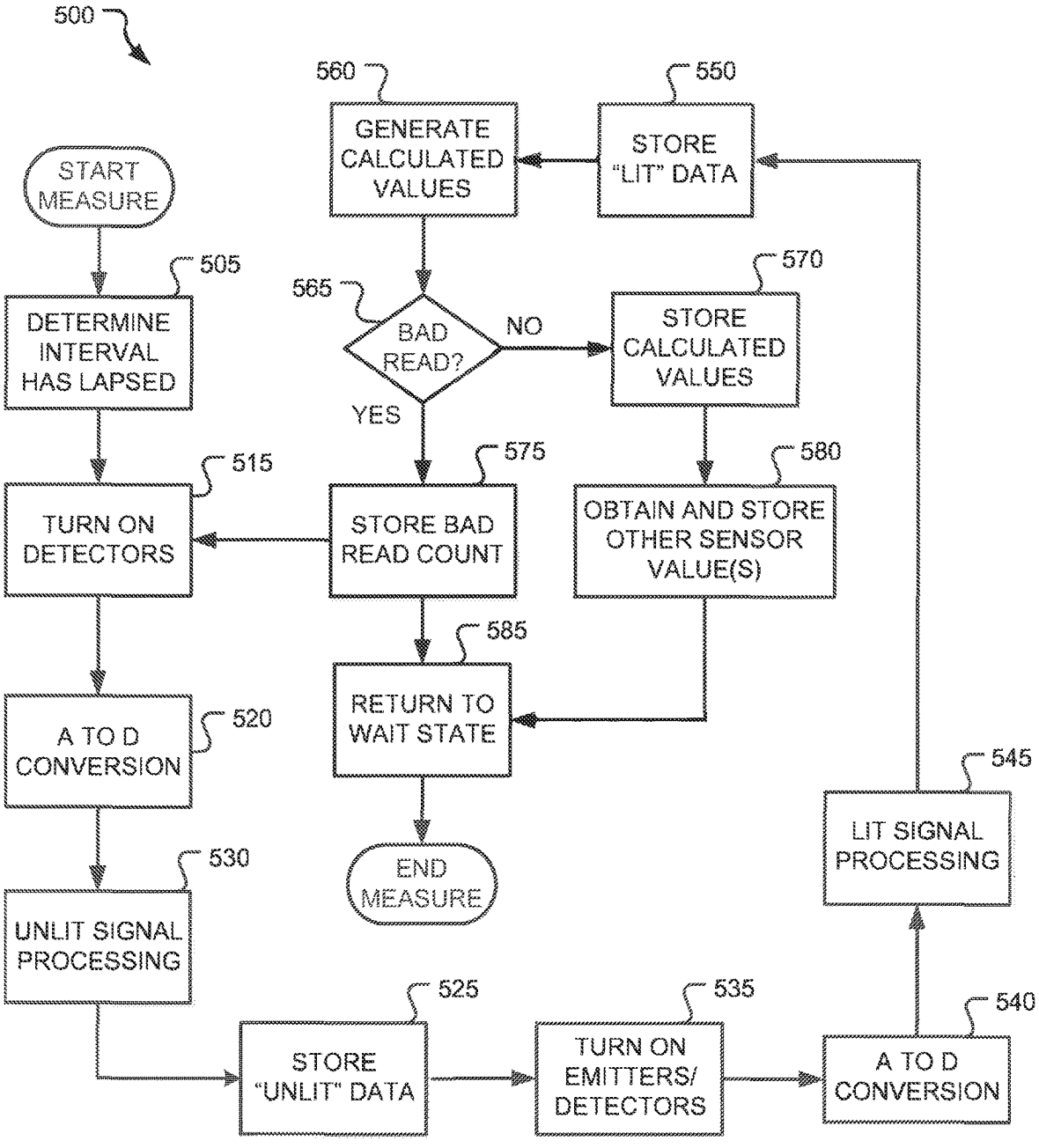
FIGURE 4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START MEASURE
505
DETERMINE INTERVAL HAS LAPSED
515
TURN ON DETECTORS
520
A TO D CONVERSION
530
UNLIT SIGNAL PROCESSING
525
STORE "UNLIT" DATA
535
TURN ON EMITTERS/ DETECTORS
540
A TO D CONVERSION
545
LIT SIGNAL PROCESSING
550
STORE "LIT" DATA
560
GENERATE CALCULATED VALUES
565
BAD READ?
NO
YES
570
STORE CALCULATED VALUES
575
STORE BAD READ COUNT
580
OBTAIN AND STORE OTHER SENSOR VALUE(S)
585
RETURN TO WAIT STATE
END MEASURE

FIGURE 5

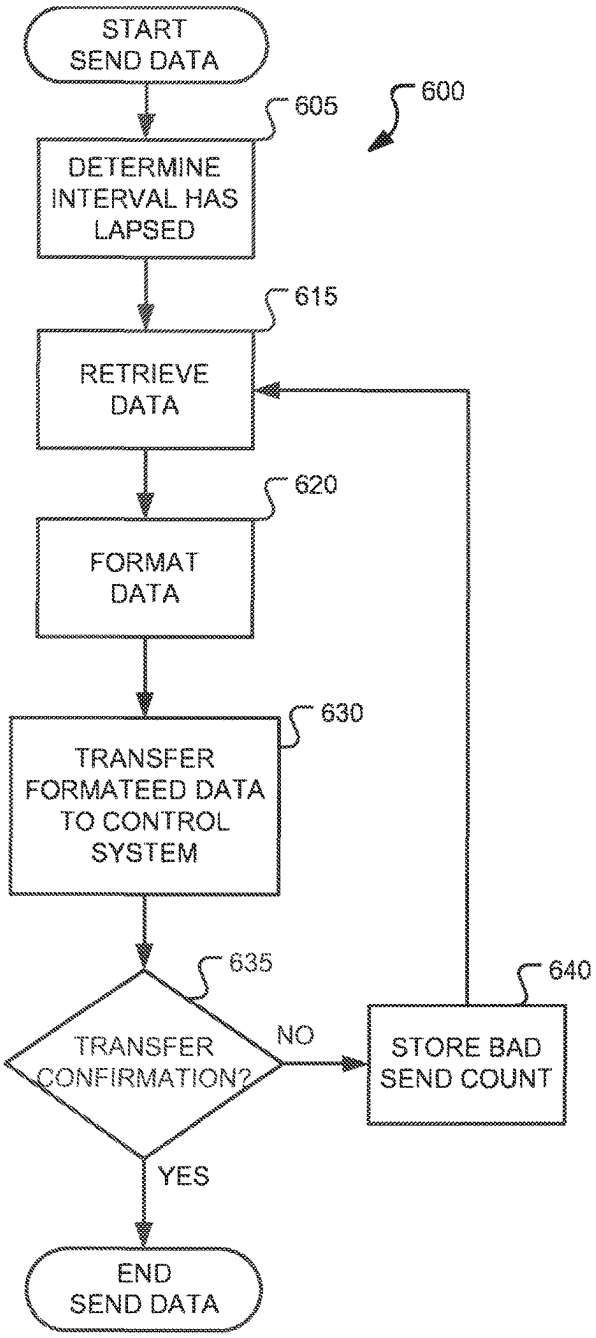


FIGURE 6A

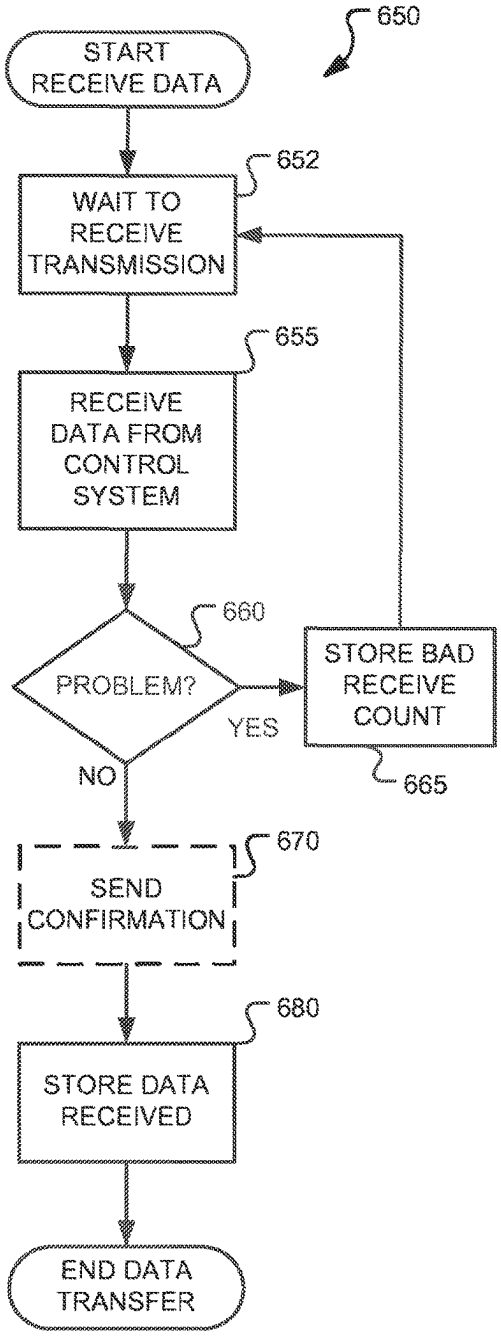


FIGURE 6B

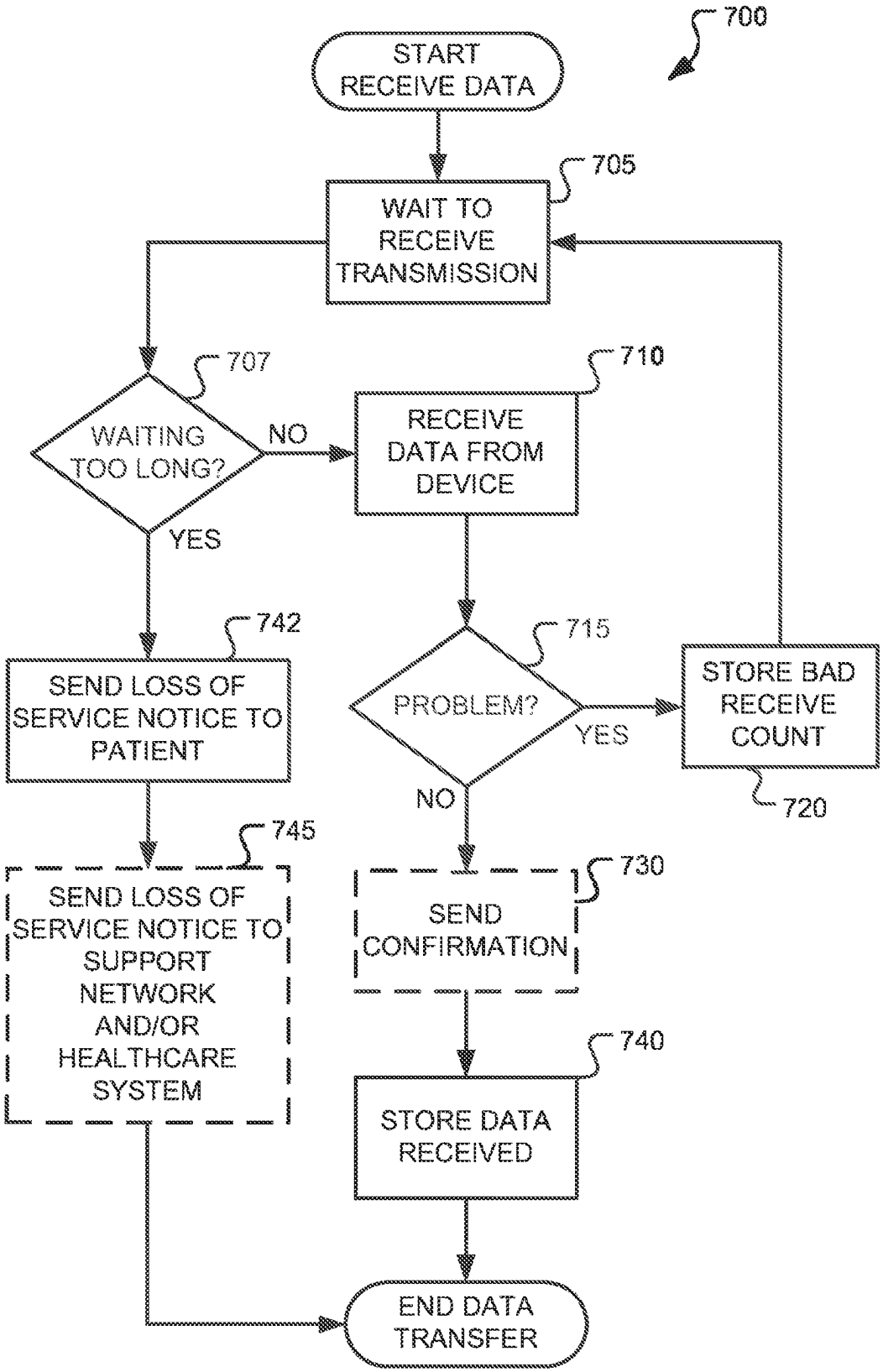

700
START RECEIVE DATA
705
WAIT TO RECEIVE TRANSMISSION
707
WAITING TOO LONG?
NO
YES
710
RECEIVE DATA FROM DEVICE
715
PROBLEM?
YES
NO
STORE BAD RECEIVE COUNT
720
742
SEND LOSS OF SERVICE NOTICE TO PATIENT
745
SEND LOSS OF SERVICE NOTICE TO SUPPORT NETWORK AND/OR HEALTHCARE SYSTEM
730
SEND CONFIRMATION
740
STORE DATA RECEIVED
END DATA TRANSFER

FIGURE 7

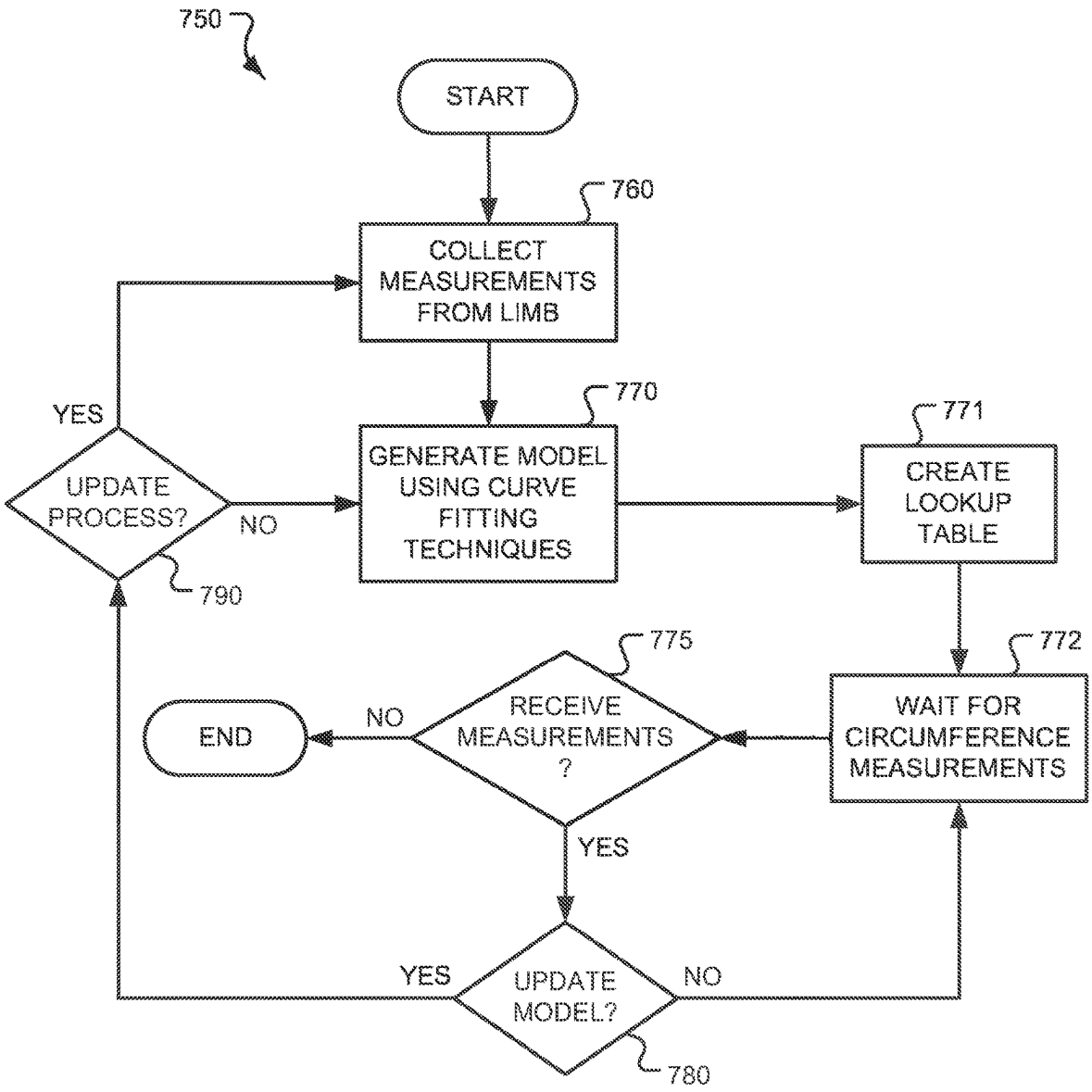

750
START
760
COLLECT MEASUREMENTS FROM LIMB
770
GENERATE MODEL USING CURVE FITTING TECHNIQUES
771
CREATE LOOKUP TABLE
772
WAIT FOR CIRCUMFERENCE MEASUREMENTS
775
RECEIVE MEASUREMENTS ?
NO
END
YES
UPDATE MODEL?
YES
NO
780
UPDATE PROCESS?
YES
NO
790

FIGURE 8A

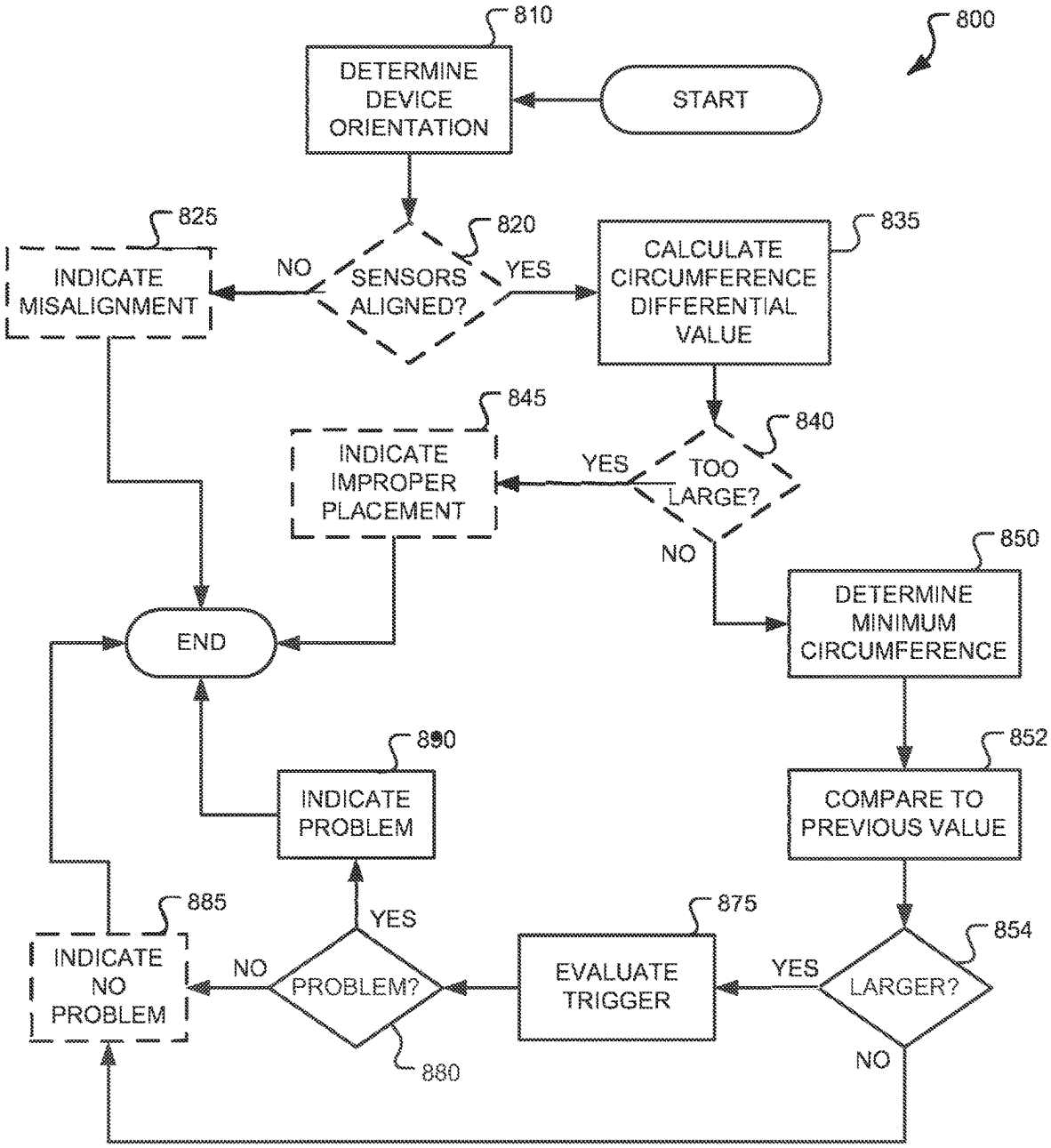

800
810
DETERMINE DEVICE ORIENTATION
START
825
INDICATE MISALIGNMENT
820
NO
SENSORS ALIGNED?
YES
835
CALCULATE CIRCUMFERENCE DIFFERENTIAL VALUE
845
INDICATE IMPROPER PLACEMENT
840
YES
TOO LARGE?
NO
850
DETERMINE MINIMUM CIRCUMFERENCE
END
890
INDICATE PROBLEM
852
COMPARE TO PREVIOUS VALUE
885
INDICATE NO PROBLEM
YES
NO
PROBLEM?
880
875
EVALUATE TRIGGER
YES
854
LARGER?
NO

FIGURE 8B

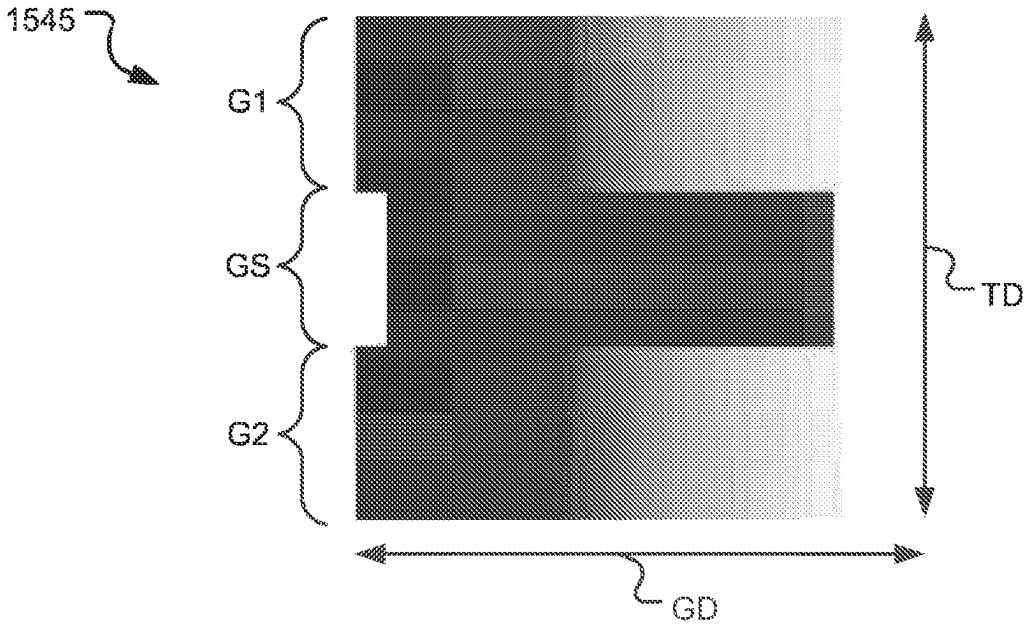


FIGURE 9

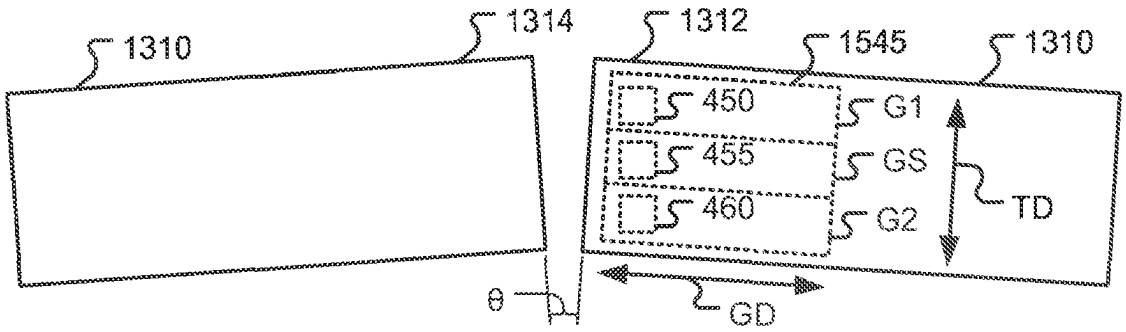


FIGURE 10A

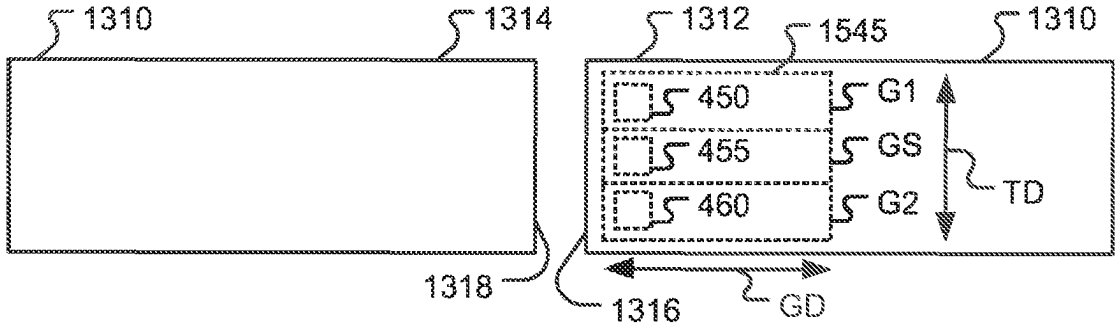


FIGURE 10B

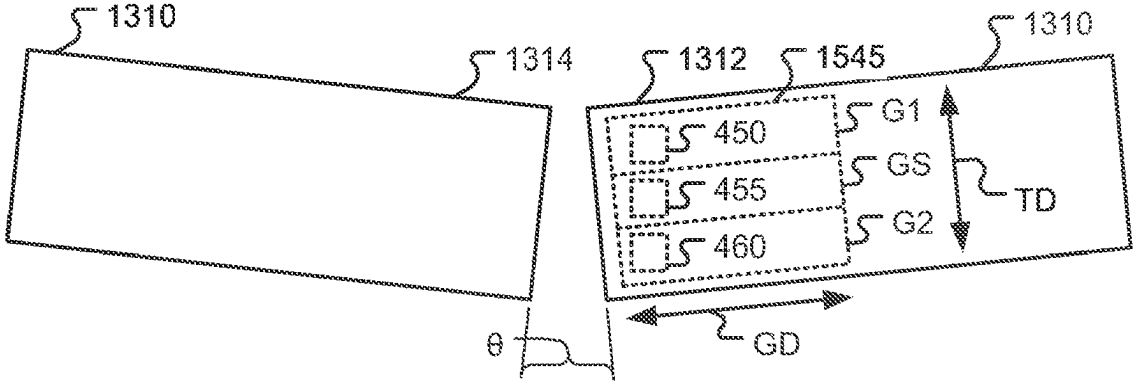


FIGURE 10C

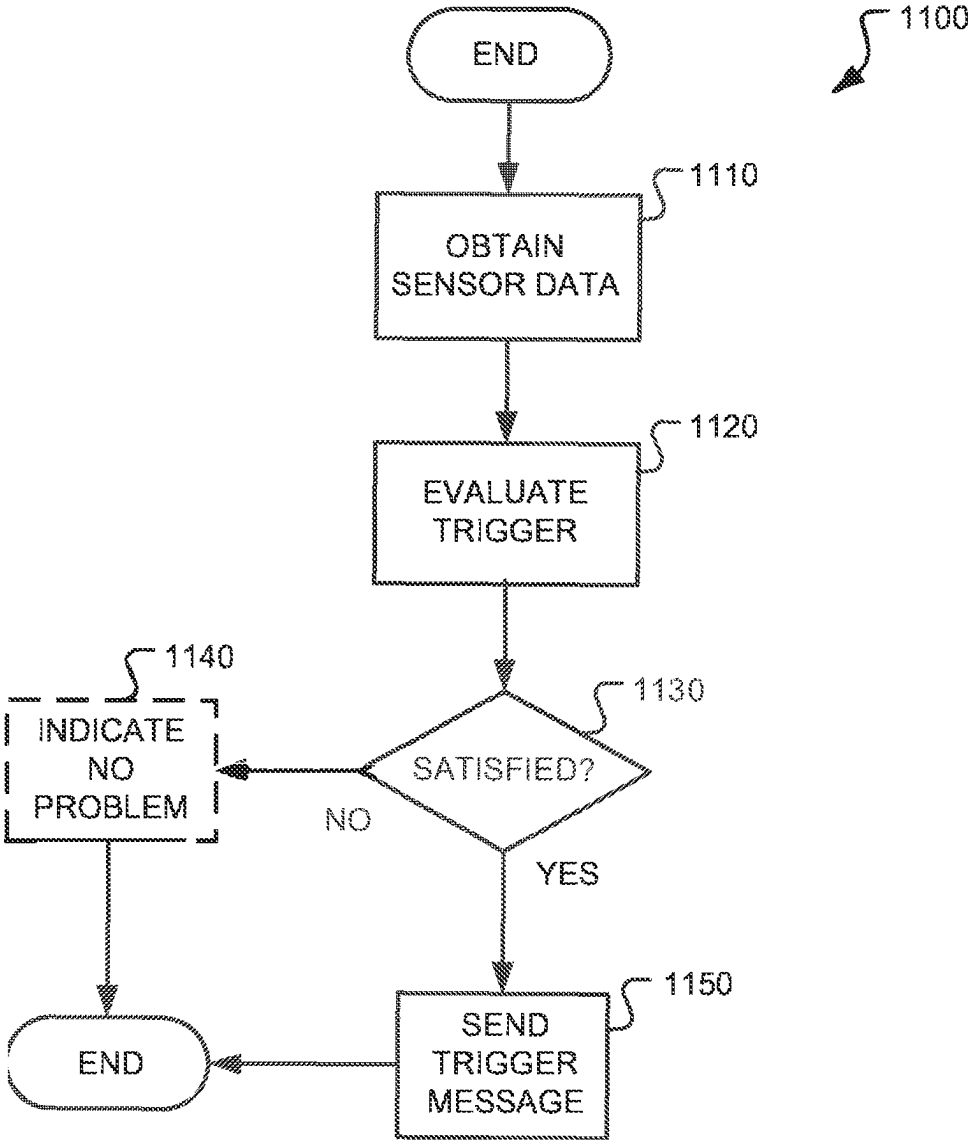

1100
END
1110
OBTAIN SENSOR DATA
1120
EVALUATE TRIGGER
1130
SATISFIED?
NO
YES
1140
INDICATE NO PROBLEM
1150
SEND TRIGGER MESSAGE
END

FIGURE 11

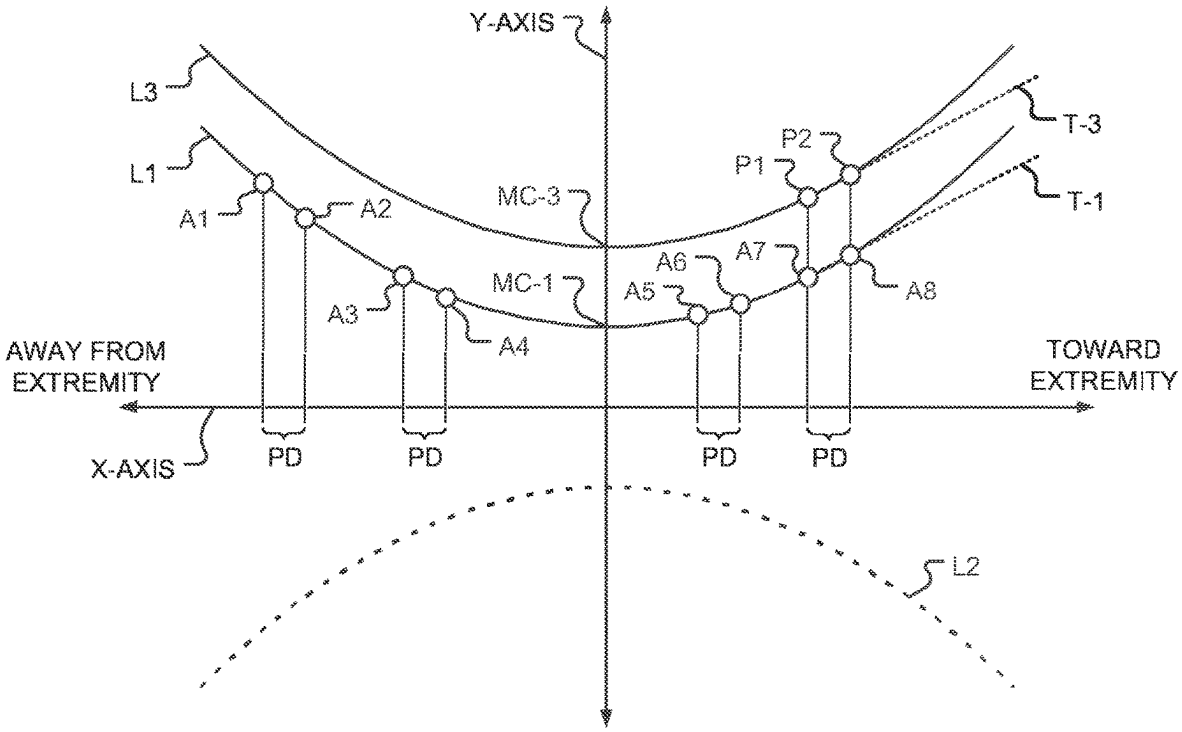

Y-AXIS
L3
L1
A1
A2
A3
A4
MC-3
MC-1
A5
A6
A7
A8
P1
P2
T-3
T-1
AWAY FROM EXTREMITY
TOWARD EXTREMITY
X-AXIS
PD
PD
PD
PD
L2

FIGURE 12

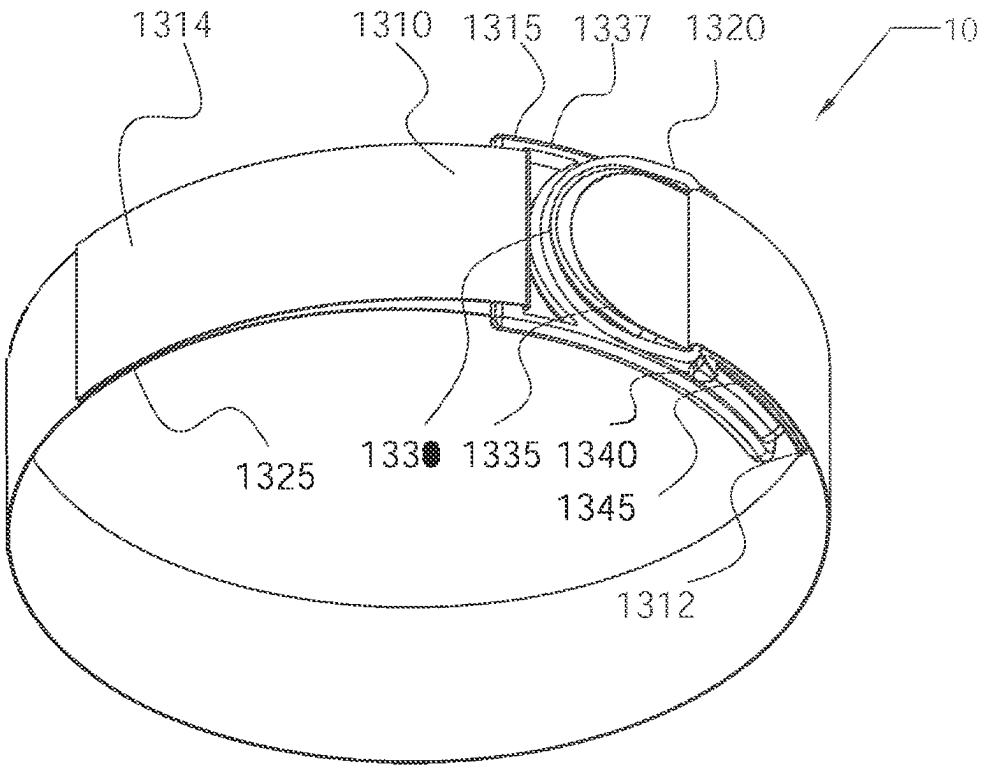


FIGURE 13

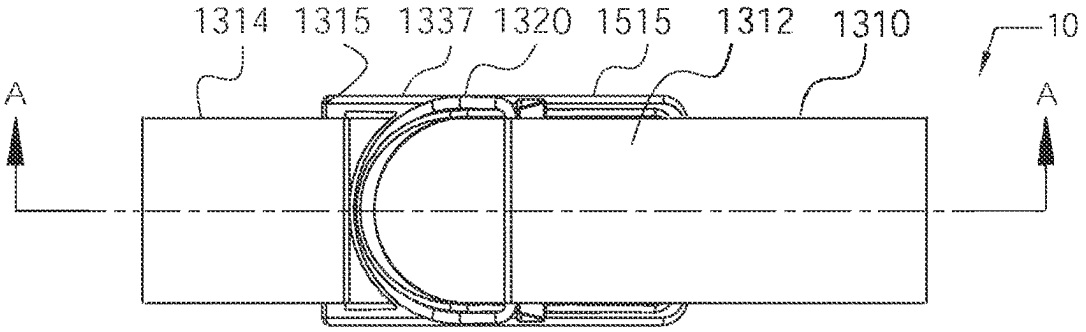


FIGURE 14

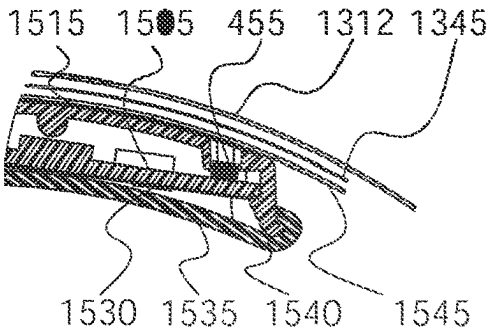
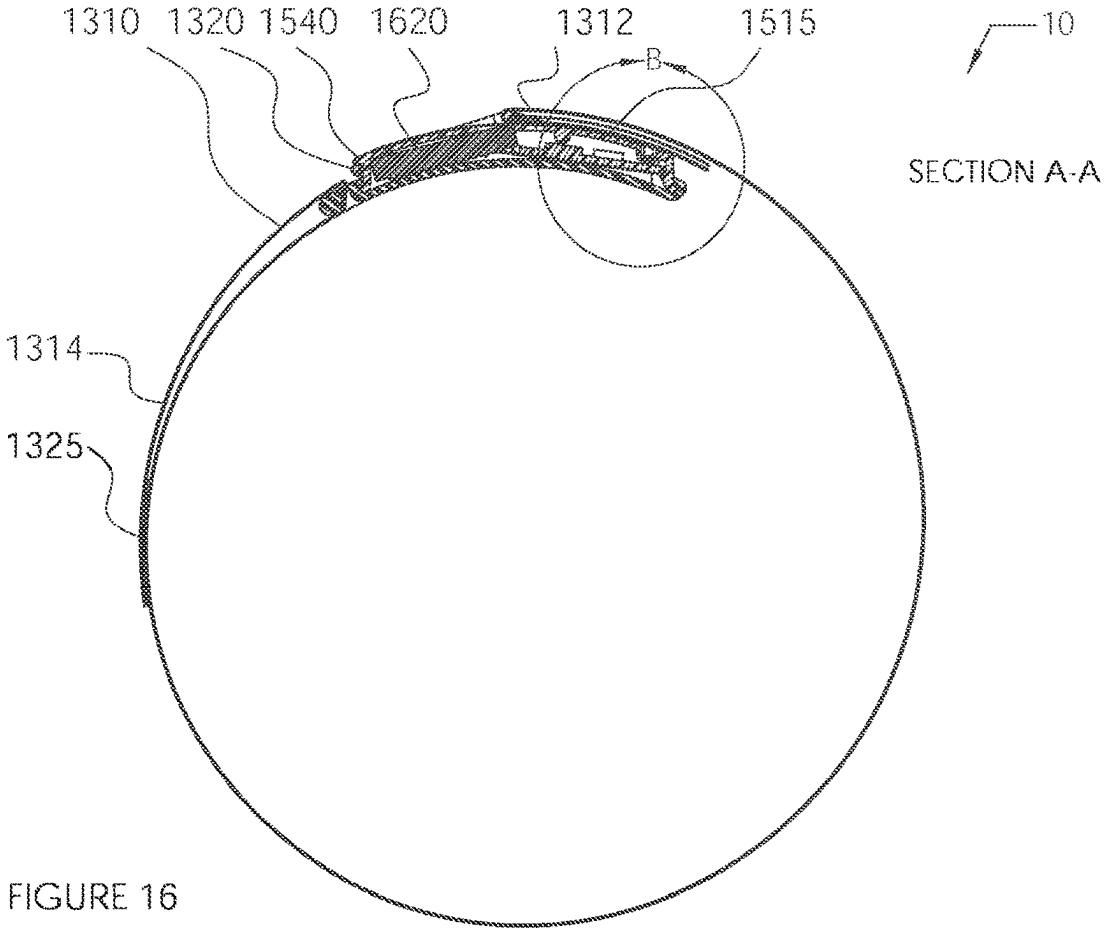


FIGURE 15

DETAIL B



SECTION A-A

FIGURE 16

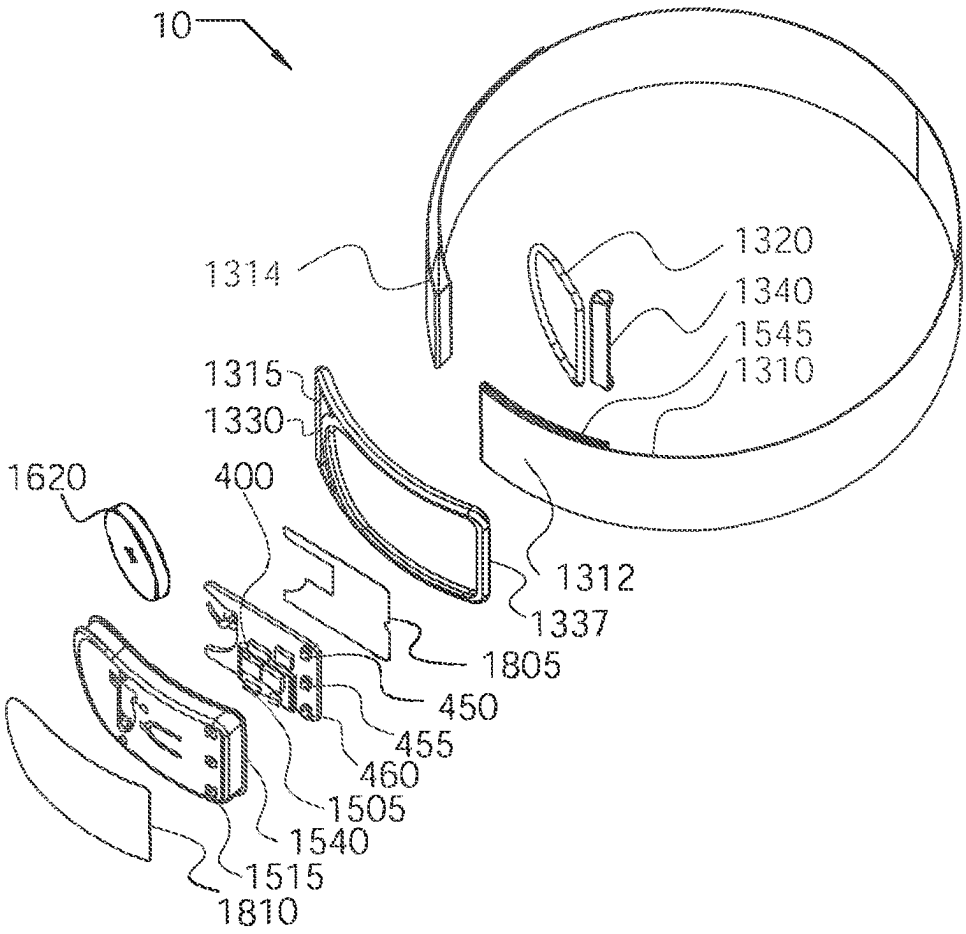

10
1314
1320
1340
1545
1310
1315
1330
1620
400
1312
1337
1805
450
455
460
1505
1540
1515
1810

FIGURE 17

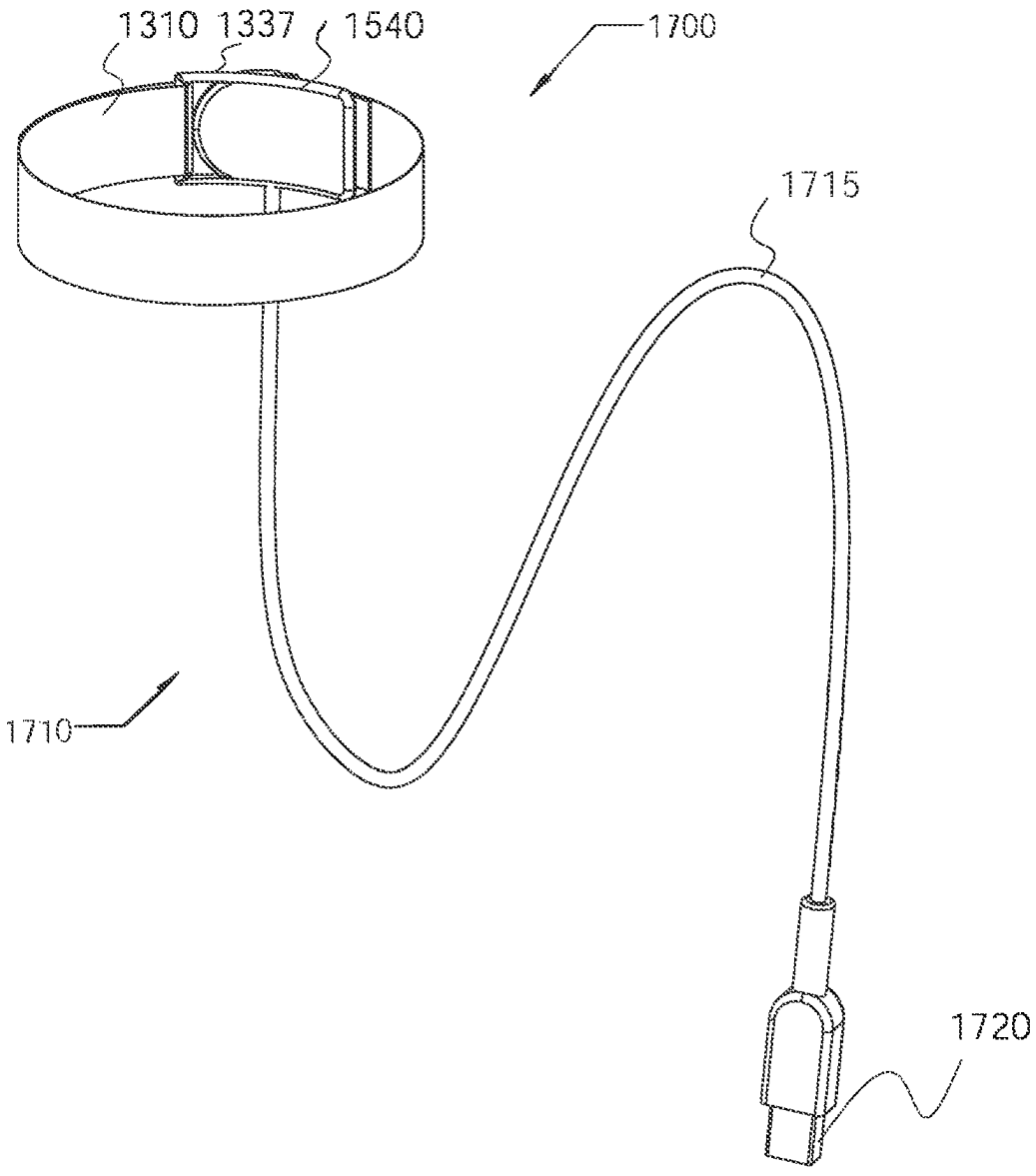


FIGURE 18

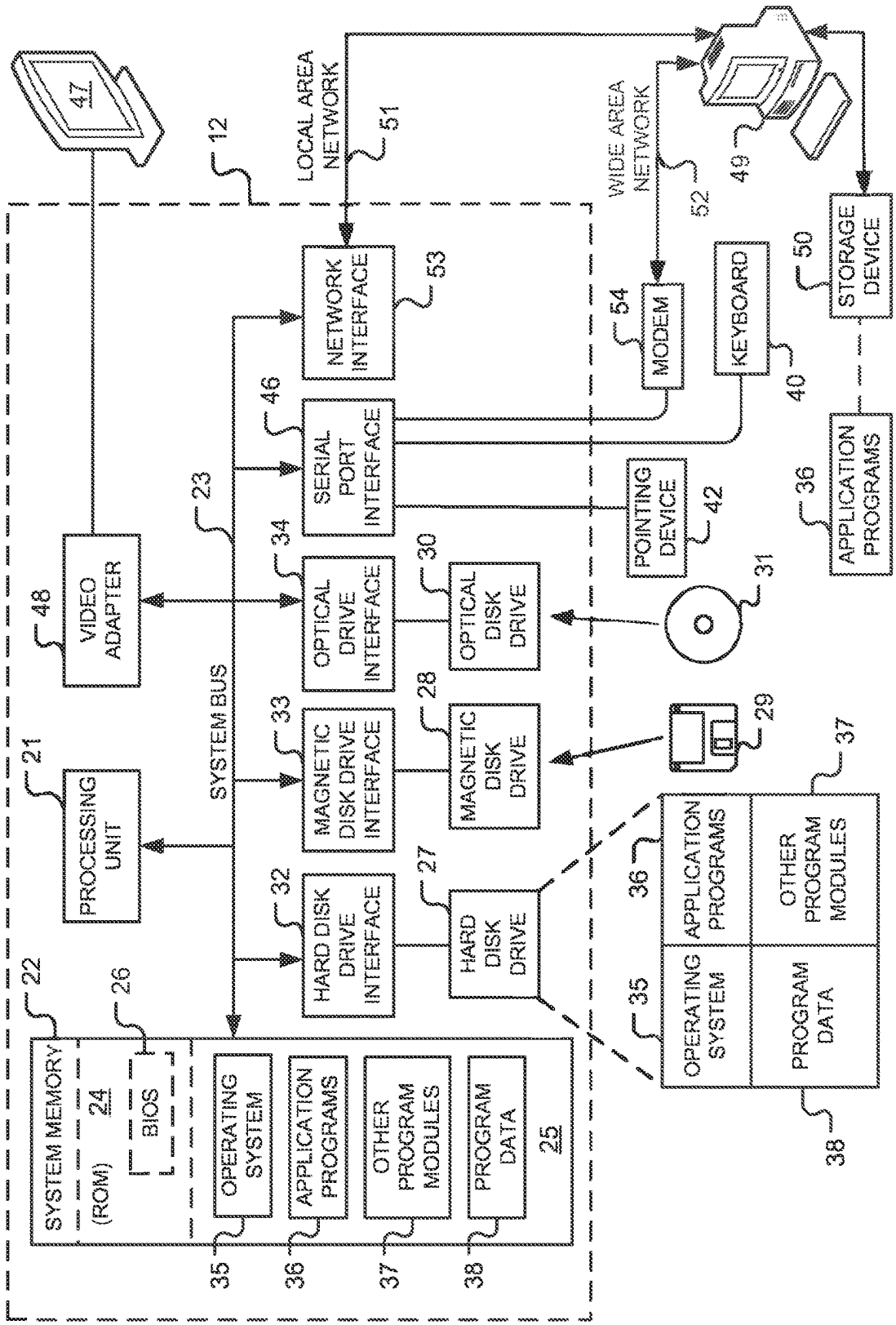

47
12
LOCAL AREA NETWORK
51
WIDE AREA NETWORK
52
49
NETWORK INTERFACE
53
54
MODEM
KEYBOARD
50
STORAGE DEVICE
40
46
SERIAL PORT INTERFACE
APPLICATION PROGRAMS
36
POINTING DEVICE
42
23
34
OPTICAL DRIVE INTERFACE
30
OPTICAL DISK DRIVE
31
48
VIDEO ADAPTER
SYSTEM BUS
33
MAGNETIC DISK DRIVE INTERFACE
28
MAGNETIC DISK DRIVE
29
21
PROCESSING UNIT
32
HARD DISK DRIVE INTERFACE
27
HARD DISK DRIVE
36
APPLICATION PROGRAMS
37
OTHER PROGRAM MODULES
35
OPERATING SYSTEM
PROGRAM DATA
38
22
SYSTEM MEMORY
(ROM) 24
26
BIOS
OPERATING SYSTEM
APPLICATION PROGRAMS
OTHER PROGRAM MODULES
PROGRAM DATA
25
35
36
37
38

FIGURE 19

SYSTEM AND METHOD FOR PATIENT MONITORING

CROSS-REFERENCE TO RELATED PATENT APPLICATION

This application is a continuation of U.S. application Ser. No. 14/481,742, filed on Sep. 9, 2014 (now U.S. Pat. No. 10,993,658), and titled "SYSTEM AND METHOD FOR PATIENT MONITORING," which is a continuation of U.S. application Ser. No. 12/987,985, filed on Jan. 10, 2011 (now U.S. Pat. No. 8,827,930), and titled "SYSTEM AND METHOD FOR PATIENT MONITORING," which are herein incorporated by reference in their entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention is directed generally to devices and methods for monitoring patient health, and more particularly, to methods and systems for detecting edema.

2. Description of the Related Art

Monitoring patient parameters is quite common in medical care environments, such as hospitals, doctors' offices, and the like. Further, patient monitoring outside of a clinical setting is increasing because of the rising cost of traditional healthcare. There is a need for devices configured to monitor a patient's health. Devices configured to notify professional healthcare providers when appropriate are particularly desirable.

A "compensated" system is able to function despite any stressors or defects that might be present. Decompensation occurs when the system can no longer compensate for these issues. Decompensation is a general term commonly used in medicine to describe a variety of situations.

Cells are surrounded by an extracellular fluid that includes interstitial fluid, plasma, and transcellular fluid. The interstitial fluid is found in the interstitial spaces, also known as the tissue spaces. Edema is an abnormal accumulation of fluid in the interstitial spaces that causes swelling.

Edema in the feet and legs is often referred to as peripheral edema. Limb volume changes have sufficient specificity and sensitivity to be predictive of impending heart failure decompensation in some forms of heart failure. The physiological conditions that cause an increase in interstitial fluid in the limbs of a heart failure patient may also cause decompensation. Therefore, edema may be predictive of congestive chest conditions that can endanger the patient.

There are several traditional methods of measuring or evaluating edema. The most commonly used method is to press a depression into the skin (e.g., of the lower leg) and assign a grade (e.g., on a 1 to 4 scale) indicating an amount of edema present based on the depth and persistence of the depression. This method provides a coarse but useful measure of edema.

More accurate methods of measuring or evaluating edema include placing the patient's limb in a container of water and measuring an amount of fluid displaced by the patient's limb. By collecting two or more displacement measurements, a change in limb volume, if any, that occurred between measurements can be determined. Unfortunately, this method is wet, cumbersome, and unsuitable for continuous patient monitoring and data collection.

A Leg-O-Meter device may be used to measure edema. The Leg-O-Meter device includes a tape measure positioned at a predetermined height above the floor. The tape measure is used to determine a single distance around a limb. While results obtained by the Leg-O-Meter device are well correlated with those obtained using the more cumbersome fluid displacement method, the Leg-O-Meter device requires a skilled practitioner to operate and the active involvement of the patient.

Electronic measurement devices also exist that are large, expensive, and fixed making them unsuitable for a home environment. Further, such devices typically do not provide methods of communicating with the patient, a caregiver, or a healthcare provider. These devices also do not typically analyze the data collected.

Quantifying and monitoring peripheral edema is important because the onset of edema and/or changes in an amount of edema present can occur many days prior to a considerable decline in patient health. In other words, the onset of edema and/or changes in an amount of edema present may predict (e.g., by several days) a significant decline in a patient's health. This predictive indication may be used in some cases to avoid a significant decline in patient health. For example, such early warning of an impending problem may be used to adjust the patient's diet, salt intake, medications, and the like. Further, consultation with healthcare professionals before the decline occurs may avoid precipitous health declines, such as, but not limited to, decompensated heart failure. Therefore, a need exists for methods and systems that provide substantially continuous monitoring of edema. A need also exists for methods and systems that track a patient's physiological parameters and symptoms for the purposes of detecting trends and/or recognizing impending patient health conditions that may require medical intervention, such as hospitalization.

The present application provides these and other advantages as will be apparent from the following detailed description and accompanying figures.

BRIEF DESCRIPTION OF THE DRAWINGS

The detailed description is described with reference to the accompanying figures, in which the leftmost digit(s) of a reference number identifies the figure in which the reference number first appears. The use of the same reference numbers in different figures indicates similar or identical items.

FIG. **1** is a diagram of a system configured to detect edema.

FIG. **2** is a diagram of a control loop implemented by the system of FIG. **1**.

FIG. **3** is a diagram of an embodiment of the system of FIG. **1**.

FIG. **4** is a diagram of an exemplary circuit that may be used to construct a device worn on a patient's limb configured to collect patient data used by a control system to determine a circumference of the patient's limb.

FIG. **5** is a flow diagram of a method of collecting patient data performed the device worn on a patient's limb.

FIG. **6**A is a flow diagram of a method of transmitting the patient data collected to the control system.

FIG. **6**B is a flow diagram of a method performed the device worn on a patient's limb when receiving messages and/or data from the control system.

FIG. **7** is a flow diagram of a method performed by the control system when receiving the patient data from the device worn on a patient's limb.

FIG. **8**A is a flow diagram of a method of constructing a model of the patient's limb.

FIG. **8**B is a flow diagram of a method of analyzing the patient data performed by the control system.

FIG. **9** is an illustration of an exemplary optical gradient that may be used to construct the device worn on a patient's limb.

FIG. **10**A is an illustration the device positioned on the patient's limb at a location above a minimum circumference of the patient's limb depicting a strap, optical gradient, and sensors that may be used to construct the device.

FIG. **10**B is an illustration the device positioned on the patient's limb at the location of the minimum circumference of the patient's limb depicting the strap, optical gradient, and sensors that may be used to construct the device.

FIG. **10**C is an illustration the device positioned on the patient's limb at a location below the minimum circumference of the patient's limb depicting the strap, optical gradient, and sensors that may be used to construct the device.

FIG. **11** is a flow diagram of a method of analyzing the patient data received from the device worn on a patient's limb performed by the control system.

FIG. **12** is a graph illustrating the patient data a model of the patient's limb.

FIG. **13** is a perspective view of an embodiment of the device worn on a patient's limb.

FIG. **14** is front view of the device of FIG. **13**.

FIG. **15** is an enlarged cross-sectional view of a portion of the device cross-sectioned along the A-A line of FIG. **13**.

FIG. **16** is cross-sectional view of the device cross-sectioned along the A-A line of FIG. **13**.

FIG. **17** is an exploded perspective view of the device of FIG. **13**.

FIG. **18** is a perspective view of an alternate embodiment of the device of FIG. **13**.

FIG. **19** is a diagram of a hardware environment and an operating environment in which one or more of the computing devices of the system of FIG. **1** may be implemented.

DETAILED DESCRIPTION

Overview

Referring to FIG. **1**, the present application describes a system **200** that includes a device **10** worn by a patient **230** that is connected (e.g., wirelessly) to a control system **220**. The control system **220** may be connected (e.g., wirelessly) to a healthcare system **205**, a support network **210**, and the like. The healthcare system **205** includes healthcare professionals, physicians, hospitals, pharmacies, and the like. The support network **210** includes the patient's friends, family, as well as others involved in the patient's care. The patient **230**, support network **210**, and/or the healthcare system **205** may provide reference information **215** to the control system **220**. The reference information **215** is used to setup or configure the control system **220**. By way of a non-limiting example, the reference information **215** may include patient information (e.g., age, height, weight), patient diagnosis, message routing information, and trigger values. The reference information **215** may also include instructions (e.g., patient instructions) associated with the trigger values. Such instructions may include a predetermined prescribed treatment plan (e.g., instructions to increase a dosage of a diuretic or other medication), instructions to perform a stress test, requests for patient symptom information, instructions to contact healthcare professional, and the like. The reference information **215** may have been provided to a website **217** generated by an optional web server **318** (illustrated in FIG. **3**) and forwarded to the control system **220** by the web server **318**.

The control system **220** may issue messages **225** to the patient **230** that could cause a modification in the patient's state **235** (e.g., reduce edema or likelihood of edema). When triggered by trigger values, the messages **225** may include one or more instructions associated with the trigger values.

The device **10** is configured to be worn on the patient's limb **11** continuously or occasionally for periods of time. When worn in this manner, the device **10** occasionally (e.g., periodically) collects data that may be processed by the control system **220** to obtain a distance measurement around the patient's limb **11**. The distance measurement is referred to herein as a "circumference measurement," independently of whether the portion of the limb whereat the measurement was taken has a substantially circular cross-sectional shape.

The data collected by the device **10** is sent to the control system **220** in a device message **240**. The control system **220** analyzes the data received from the device **10** to determine a circumference measurement for the limb **11**. Over time, multiple circumference measurements may be collected and tracked for the purposes of detecting a trend or sudden change in the circumference of the limb **11**. The previously obtained (or historical) circumference measurements may be stored in the reference information **215**.

A healthcare provider or system **205** may access the control system **220** to review the circumference measurement(s) to detect potential problems and/or recommend treatments or changes in treatment. Further, when the control system detects a trend or sudden change in the circumference of the limb **11**, the control system **220** may send messages to the healthcare system **205**, the support network **210**, the patient **230**, and the like. When triggered by trigger values, messages sent to the healthcare system **205**, the support network **210**, the patient **230**, and the like may include one or more instructions associated with the trigger values.

Messages sent to the healthcare system **205**, the support network **210**, and/or the patient **230** may include SMS cellular telephone messages, recorded voice messages (e.g., including educational information), alerts, alarms, and the like.

Thus, the system **200** provides a means of assessing changes in the size of the patient's limb **11**, and more particularly the onset of or changes in peripheral edema. The assessment may be conducted remotely by the control system **220** and/or the healthcare system **205**. Members of a support network **210** and/or the healthcare system **205** need not be present to collect or evaluate the circumference measurement. Instead, circumference measurements may be collected automatically by the device **10** and optionally, transferred to the system **200**. Circumference measurements may be collected on an ongoing basis over any desired length of time.

While peripheral edema is often most pronounced in the lower leg, interstitial swelling is also generally present to a lesser degree in other parts of the body. Therefore, peripheral edema may be measured in other parts of the body. For ease of illustration, the device **10** is described below and illustrated as being worn on a lower portion of a patient's leg near the ankle. However, the device **10** may also be worn on a different portion of a patient's leg (e.g., near the knee, thigh, and the like), a portion of a patient's arm (e.g., on or near the wrist, on the forearm, above the elbow, and the like), a portion of a patient's foot (e.g., on a toe), a portion of a patient's hand (e.g., on a finger), and the like. In other

words, the device **10** is not limited to being worn on any particular portion of the body.

The system **200** may be conceptualized as a continually readjusting system that seeks a stable desired condition (e.g., an absence of edema). The system **200** may implement a control loop **100** illustrated in FIG. **2**. In the control loop **100**, reference information "R" is provided and compared with feedback information "F." With respect to the system **200**, the reference information "R" may be the reference information **215** provided to the control system **220**, and the feedback information "F" may be the device messages **240** transmitted by the device **10**.

The difference between the reference information "R" and the feedback information "F" is an error "E." The error "E" is input into a controller **115**. In system **200**, the error "E" is calculated by the control system **220**. The controller **115** in turn issues commands "U" (e.g., the messages **225**) that are used to affect the state of the patient **230**. In the system **200**, the control system **220** may issue messages **225** to the patient **230**, the support network **210**, and/or the healthcare system **205**. This is reflected in a current state "Y." In FIG. **1**, the patient's current state is labeled with reference numeral **235**. The current state "Y" provides the feedback information "F" that is compared to the reference information "R." In other words, the patient's state **235** provides the device messages **240** (with data used to obtain the circumference measurement) that are compared to the reference information **215** (e.g., previously obtained circumference measurements). Based on the results of this comparison, one or more messages **225** may be sent to the patient **230**, the support network **210**, and/or the healthcare system **205** to modify the patient's state **235**.

System **300**

FIG. **3** illustrates a system **300**, which is an exemplary implementation of the system **200** (see FIG. **1**). Turning to FIG. **3**, the control system **220** includes a database server **370**. The reference information **215** (see FIG. **1**) is stored in a database server **370**. The reference information **215** may be received by the database server **370** during an initial setup process as well as on an ongoing basis. The system **300** may include the optional web server **318** configured to generate the website **217** (see FIG. **1**) to which the reference information **215** may be provided and transferred to the database server **370** (e.g., over the Internet **340** or other network). The database server **370** may also store pertinent data about the patient **230** (such as patient history, a patient record, and the like), trigger event levels (discussed below), and addresses to which messages (e.g., notifications, alerts, and the like) are to be sent.

Feedback information (e.g., the device message **240** illustrated in FIG. **1**) most often originates from the patient **230** and/or the device **10**. This feedback information can travel several alternate paths depending upon the implementation details. For example, the feedback information may be input into a computing device (e.g., a patient desktop computer **335**, a patient cellular telephone **350**, a patient portable computer **355**, and the like) connected to the database server **370** (or the web server **318**) via the Internet **340**. The device **10** may communicate with the computing device via a wired or wireless communication link (e.g., a communication link **352**). Over a wireless communication link, the device **10** may communicate with the computing device using SMS messages, WIFI protocols, Bluetooth protocols, and the like. The computing device may transfer the feedback information to the database server **370**. The device **10** may communicate the device messages **240** to the computing device for transmission thereby to the database server **370**.

In the embodiment illustrated, the patient desktop computer **335** is connected to the Internet **340** via a conventional wired connection.

In the embodiment illustrated, the patient cellular telephone **350** and the patient portable computer **355** are connected to the Internet **340** by an Internet gateway device **365** (e.g., a modem). The patient cellular telephone **350** and the patient portable computer **355** may communicate with the Internet gateway device **365** using WIFI protocols, Bluetooth protocols, and the like.

By way of a non-limiting example, the feedback information may be transmitted by the device **10** via a radio link (e.g., the radio link **352**) to the patient desktop computer **335**, the patient cellular telephone **350**, the patient portable computer **355**, and the like. By way of another non-limiting example, the feedback information may be transmitted by the device **10** directly to the Internet gateway device **365**.

The feedback information is received by the database server **370**. In the embodiment illustrated, the database server **370** implements the control system **220** (see FIG. **1**) that compares the current state **235** of the patient **230** and the reference information **215** (which may include previously received feedback information).

One or more messages **225** to be reviewed by the patient **230** may be transmitted by the database server **370** to the device **10**, the patient desktop computer **335**, the patient cellular telephone **350**, the patient portable computer **355**, and the like. By way of a non-limiting example, such messages may be displayed on the website **217** (see FIG. **2**) generated by the web server **318**. In such embodiments, the database server **370** is configured to instruct the web server **318** to display messages on the website **217**. The patient desktop computer **335**, the patient cellular telephone **350**, and/or the patient portable computer **355** may connect to the web server **318** over the Internet and display the website **217** using a conventional web browser application.

The support network **210** may include one or more computing devices (e.g., a support computing device **310**) connected to the database server **370** via the Internet **340**. One or more messages to be reviewed by a support person **330** may be transmitted by the database server **370** to the computing device **310**. By way of a non-limiting example, such messages may be displayed on the website **217** (see FIG. **2**) generated by the web server **318**. In the embodiment illustrated, the computing device **310** is connected to the Internet **340** via a wireless communication link **312** with a cellular telephone network **314**. The computing device **310** may connect to the web server **318** over the Internet and display the website **217** using a conventional web browser application. Some patients may rely on help from the support network **210** while others may have no such support.

The healthcare system **205** may include one or more computing devices (e.g., a caregiver computing device **315**) connected to the database server **370** via the Internet **340**. One or more messages to be reviewed by a caregiver **332** may be transmitted by the database server **370** to the computing device **315**. By way of a non-limiting example, such messages may be displayed on the website **217** (see FIG. **2**) generated by the web server **318**. In the embodiment illustrated, the computing device **315** is connected to the Internet **340** via a wired communication link **316**. The computing device **315** may connect to the web server **318** over the Internet and display the website **217** using a conventional web browser application.

A diagram of hardware and an operating environment in conjunction with which implementations of the database server **370**, the patient desktop computer **335**, the patient

cellular telephone **350**, the patient portable computer **355**, the support computing device **310**, the caregiver computing device **315**, and the web server **318** may be practiced is provided in FIG. **19** and described below.

Circuit **400**

FIG. **4** is a block diagram illustrating electrical components of the device **10**. The electrical components of the device **10** includes a circuit **400**, which includes an accelerometer **405**, a memory **410**, an antenna **425**, a radio **430**, a processor **435** (e.g., a CPU), an analog to digital ("A to D") converter **440**, a voltage regulator **445**, and sensors **450**, **455**, and **460**. Optionally, the circuit **400** may include an oximeter **420** and/or a heart rate sensor **415**. Optionally, the circuit **400** may include a capacitive sensor **1530** (see FIG. **15**) configured to detect the presence of the limb **11**.

The sensors **450**, **455**, and **460** each emit and detect radiation (e.g., infrared light). The sensor **450** includes an emitter "E**1**" configured to emit radiation in response to a command received from the processor **435**, and a detector "D**1**" configured to detect radiation of the type emitted by the emitter "E**1**." The sensor **450** is configured to generate an analog signal indicating how much radiation has been detected by the detector "D**1**" and transmit the analog signal to the A to D converter **440**. The detector "D**1**" may be configured to detect radiation in response to a command received from the processor **435**. The sensor **455** includes an emitter "E**2**" configured to emit radiation in response to a command received from the processor **435**, and a detector "D**2**" configured to detect radiation of the type emitted by the emitter "E**2**." The detector "D**2**" may be configured to detect radiation in response to a command received from the processor **435**. The sensor **455** is configured to generate an analog signal indicating how much radiation has been detected by the detector "D**2**" and transmit the analog signal to the A to D converter **440**. The sensor **460** includes an emitter "E**3**" configured to emit radiation in response to a command received from the processor **435**, and a detector "D**3**" configured to detect radiation of the type emitted by the emitter "E**3**." The detector "D**3**" may be configured to detect radiation in response to a command received from the processor **435**. The sensor **460** is configured to generate an analog signal indicating how much radiation has been detected by the detector "D**3**" and transmit the analog signal to the A to D converter **440**.

The A to D converter **440** is configured to digitize the analog signals received from the sensors **450**, **455**, and **460** to produce digital signals. The digital signals are then communicated to the processor **435**. The processor **435** may store the digital signals as data in the memory **410** and/or transmit the digital signals via the radio **430** and antenna **425** to an external device (e.g., with reference to FIG. **3**, the patient desktop computer **335**, the patient cellular telephone **350**, the patient portable computer **355**, the Internet gateway device **365**, and the like). By way of a non-limiting example, the radio **430** may operate at 2.4 GHz and utilize Bluetooth protocol, Bluetooth Low Energy protocol, ZigBee protocol, ANT protocol, and the like. The external device may then transmit the digital signals to the database server **370** (see FIG. **3**) via the Internet **340** (see FIG. **3**).

The processor **435** may send instructions to the voltage regulator **445** to turn off a section of the circuit **400** including the sensors **450**, **455**, and **460**, the A to D converter **440**, the optional oximeter **420**, and the optional heart rate sensor **415** to save power. Further, the processor **435** may send instructions to the voltage regulator **445** to turn on the section of the circuit including the sensors **450**, **455**, and **460**, the A to D converter **440**, the optional oximeter **420**, and the optional heart rate sensor **415**.

By way of a non-limiting example, the processor **435** may send instructions to the voltage regulator **445** to turn off the section of the circuit **400** when the capacitive sensor **1530** (see FIG. **15**) does not detect the presence of the limb **11**. Further, the processor **435** may send instructions to the voltage regulator **445** to turn on the section of the circuit **400** when the capacitive sensor **1530** (see FIG. **15**) detects the presence of the limb **11**. The capacitive sensor **1530** may be configured to generate an analog signal indicating the presence (or absence) of the limb **11** and transmit the analog signal to the A to D converter **440**. The A to D converter **440** is configured to digitize the analog signal received from the capacitive sensor **1530** to produce a digital signal that is communicated to the processor **435**. The processor **435** analyzes the digital signal and determines whether the capacitive sensor **1530** detected the presence of the limb **11**.

The circuit **400** may be connected to a battery **1620** (see FIG. **17**) and powered thereby. Error can be introduced by drift in battery voltage over time. This issue may be addressed by the voltage regulator **445**, which may be configured to provide a substantially stable voltage to the emitters "E**1**," "E**2**," and "E**3**" and detectors "D**1**," "D**2**," and "D**3**." Further, the regulated voltage provided by the voltage regulator **445** may be used by the A to D converter **440** as a reference voltage to gage and scale the voltages received from the detectors "D**1**," "D**2**," and "D**3**" when converting the voltages from analog signals to digital signals.

While in the embodiment illustrated, the circuit **400** is powered by a battery **1620**, another portable power source may be used, such as a fuel cell, storage capacitor, energy harvested from the patient **230**, energy harvested from the environment, and the like.

The accelerometer **405** may be implemented as a three-axis accelerometer configured to detect a direction of the acceleration of gravity (or gravitation force). The accelerometer **405** generates a digital signal encoding this information and communicates the signal to the processor **435**. The processor **435** may store the digital signal as device orientation data in the memory **410** and/or transmit the digital signal (or the stored device orientation data) via the radio **430** and antenna **425** to an external device (e.g., with reference to FIG. **3**, the patient desktop computer **335**, the patient cellular telephone **350**, the patient portable computer **355**, the Internet gateway device **365**, and the like). The external device may transmit the digital signal (or the device orientation data) to the database server **370** (see FIG. **3**) via the Internet **340** (see FIG. **3**). In embodiments in which the device orientation data is stored in the memory **410**, the device orientation data may be deleted from the memory **410** after the device orientation data is transmitted to the database server **370**.

The accelerometer **405** may also detect patient motion, which may be used by the control system **220** (see FIG. **2**) to determine a level of activity of the patient **230**. The accelerometer **405** generates a digital signal encoding patient motion information and communicates the signal to the processor **435**. The processor **435** may store the digital signal as patient motion information (e.g., in an activity log) in the memory **410** and/or transmit the digital signal (or the stored patient motion information) via the radio **430** and antenna **425** to an external device (e.g., with reference to FIG. **3**, the patient desktop computer **335**, the patient cellular telephone **350**, the patient portable computer **355**, the Inter-

net gateway device **365**, and the like). The external device may transmit the digital signal (or the patient motion information) to the database server **370** (see FIG. **3**) via the Internet **340** (see FIG. **3**). In embodiments in which the patient motion information is stored in the memory **410**, the patient motion information may be deleted from the memory **410** after the patient motion information is transmitted to the database server **370**.

The optional heart rate sensor **415** senses the heart rate of the patient **230** and generates an analog heart rate signal encoding this information. The analog heart rate signal is transmitted to the A to D converter **440**, which converts the analog heart rate signal to a digital heart rate signal and transmits the digital heart rate signal to the processor **435**. The processor **435** may store the digital signal as heart rate information in the memory **410** and/or transmit the digital signal (or the stored heart rate information) via the radio **430** and antenna **425** to an external device (e.g., with reference to FIG. **3**, the patient desktop computer **335**, the patient cellular telephone **350**, the patient portable computer **355**, the Internet gateway device **365**, and the like). The external device may transmit the digital signal (or the heart rate information) to the database server **370** (see FIG. **3**) via the Internet **340** (see FIG. **3**). In embodiments in which the heart rate information is stored in the memory **410**, the heart rate information may be deleted from the memory **410** after the heart rate information is transmitted to the database server **370**.

The optional oximeter **420** may be implemented as a SpO2 emitter detector circuit. The optional oximeter **420** senses the blood oxygen of the patient **230** and generates an analog blood oxygen signal encoding this information. The analog blood oxygen signal is transmitted to the A to D converter, which converts the analog blood oxygen signal to a digital blood oxygen signal and transmits the digital blood oxygen signal to the processor **435**. The processor **435** may store the digital signal as oxygen information in the memory **410** and/or transmit the digital signal (or the stored oxygen information) via the radio **430** and antenna **425** to an external device (e.g., with reference to FIG. **3**, the patient desktop computer **335**, the patient cellular telephone **350**, the patient portable computer **355**, the Internet gateway device **365**, and the like). The external device may transmit the digital signal (or the oxygen information) to the database server **370** (see FIG. **3**) via the Internet **340** (see FIG. **3**). In embodiments in which the oxygen information is stored in the memory **410**, the oxygen information may be deleted from the memory **410** after the oxygen information is transmitted to the database server **370**.

The capacitive sensor **1530** (see FIG. **15**) senses whether the limb **11** is present and generates an analog or digital signal encoding this information. The signal is transmitted to the processor **435** (optionally via the A to D converter for conversion from an analog signal to a digital signal, if necessary). The processor **435** is configured to place the device **10** in a sleep mode if the signal indicates the limb **11** is not present and to maintain the device **10** in the sleep mode until the signal indicates the limb **11** is detected.

Methods

FIG. **5** is a flow diagram of a method **500** performed by the processor **435**. The method collects data using the sensor **450**, **455**, and **460** that is subsequently used by the control system **220** to obtain a circumference measurement. When the method **500** begins, the processor **435** is in a wait state.

In block **505**, the processor **435** determines a predetermined measurement interval has lapsed since data was last collected by the device **10**. At this point, the processor **435** may turn on the voltage regulator **440** to allow it to stabilize. As mentioned above, the voltage regulator **440** may be used to power the detectors "D**1**," "D**2**," and "D**3**" and the emitters "E**1**," "E**2**," and "E**3**." The voltage regulator **440** may also power the optional oximeter **420** and/or the optional heart rate sensor **415**. Thus, turning on the voltage regulator **440** may also turn on the optional oximeter **420** and/or the optional heart rate sensor **415**.

Then, in block **515**, the processor **435** turns on the detectors "D**1**," "D**2**," and "D**3**" of the sensors **450**, **455**, and **460**, respectively, while, the emitters "E**1**," "E**2**," and "E**3**" remain unlit (i.e., not emitting radiation). The detectors "D**1**," "D**2**," and "D**3**" each sense an amount of radiation and generate an "unlit" analog signal indicating the amount of radiation detected when the emitters "E**1**," "E**2**," and "E**3**" are unlit. Thus, an amount of ambient or background radiation may be detected and used to correct subsequent measurements.

In block **520**, the A to D converter **440** receives the "unlit" analog signals from the detectors "D**1**," "D**2**," and "D**3**," digitizes the "unlit" analog signals to produce "unlit" digital signals, and transmits the "unlit" digital signals to the processor **435** for processing.

In block **530**, the processor **435** processes the "unlit" digital signals. As is apparent to those of ordinary skill in the art, variation in emitter efficiency and detector sensitivity caused by manufacturing tolerances and position variation may be addressed by calibrating the circuit **400** (see FIG. **4**). For example, the circuit **400** may be calibrated initially against a gold standard reflective surface and differences between the voltages received from the detectors "D**1**," "D**2**," and "D**3**" of the sensors **450**, **455**, and **460** stored and used as calibration data. In block **530**, the processor **435** may adjust the "unlit" digital signals using the calibration data. For example, the calibration data may be subtracted from the "unlit" digital signals to equalize the differential efficiencies of emitter/detector pairs of the sensors **450**, **455**, and **460**.

In block **525**, the processor **400** may store the "unlit" digital signals and/or the processed "unlit" digital signals in the memory **410** as "unlit" data.

Then, in block **535**, the processor **435** turns on both the emitters "E**1**," "E**2**," and "E**3**" and the detectors "D**1**," "D**2**," and "D**3**" simultaneously.

The detectors "D**1**," "D**2**," and "D**3**" each sense an amount of radiation and generate a "lit" analog signal indicating the amount of radiation detected when the emitters "E**1**," "E**2**," and "E**3**" are lit.

In block **540**, the A to D converter **540** receives the "lit" analog signals from the detectors "D**1**," "D**2**," and "D**3**," digitizes the "lit" analog signals to produce "lit" digital signals, and transmits the "lit" digital signals to the processor **435** for processing.

In block **545**, the processor **435** processes the "lit" digital signals. In block **530**, the processor **435** may adjust the "lit" digital signals using the calibration data. For example, the calibration data may be subtracted from the "lit" digital signals to equalize the differential efficiencies of emitter/detector pairs of the sensors **450**, **455**, and **460**.

In block **550**, the processor **435** stores the "lit" digital signals and/or the processed "lit" digital signals in the memory **410** as "lit" data.

In block **555**, the processor **435** generates calculated values for each of the "lit" digital signals. The calculated values may be determined by subtracting the "unlit" digital signals from the "lit" digital signals. Thus, the calculated values reflect an amount of radiation emitted by the emitters "E**1**," "E**2**," and "E**3**" and subsequently detected by the

detectors "D1," "D2," and "D3." Further, the calculated values include a value for each of the sensors **450**, **455**, and **460**.

In decision block **565**, the processor **435** evaluates read quality. Read quality may be determined by comparing the calculated values obtained from the detectors "D1" and "D3" with a predetermined "normal" range. If the calculated values are outside the predetermined "normal" range, the processor **435** determines a bad read has occurred. Otherwise, if the calculated values are inside the predetermined "normal" range, the processor **435** determines a good read has occurred.

Optionally, in decision block **565**, the calculated values obtained from the detectors "D1" and "D3" may be compared to one another to determine whether the values differ from one another by less than a predetermined minimum amount or more than a predetermined maximum amount. If the calculated values differ from one another by less than the predetermined minimum amount or more than the predetermined maximum amount, the processor **435** determines a bad read has occurred. Otherwise, if the calculated values differ from one another by at least the predetermined minimum amount and no more than the predetermined maximum amount, the processor **435** determines a good read has occurred.

As will be explained below, when the device **10** is properly positioned on the limb **11** of the patient **230**, the calculated value for the detector "D2" is within a predetermined range because the detector "D2" is adjacent a solid portion "GS" (see FIG. **9**) of an optical gradient **1545** (see FIG. **9**) having a substantially constant reflectivity. If the calculated value for the detector "D2" is not within the predetermined range, the processor **435** determines a bad read has occurred. On the other hand, if the calculated value for the detector "D2" is within the predetermined range, the processor **435** determines a good read has occurred.

The decision in decision block **565** is "YES," when a "bad" read has occurred. On the other hand, the decision in decision block **565** is "NO," when an acceptable read has occurred.

When the decision in decision block **565** is "NO," in block **570**, the processor **435** stores the calculated values in the memory **410**.

In block **580**, the processor **435** obtains one or more accelerometer values from the accelerometer **405** and stores the accelerometer value(s) in the memory **410**. The accelerometer value(s) may include an activity log that includes information about patient activity levels. In block **580**, the processor **435** may also obtain data from the oximeter **420** and/or the heart rate sensor **415** and store that data in the memory **410**.

Then, in block **585**, the processor **435** returns to the wait state and the method **500** terminates.

When the decision in decision block **565** is "YES," in block **575**, the processor **435** stores a bad read count in the memory **410** and returns to block **515**. In block **575**, the processor **435** may also evaluate the number of bad reads stored and set an error flag, if required.

Then, in block **585**, the processor **435** returns to the wait state and the method **500** terminates.

FIG. **6**A is a flow diagram of a method **600** of transferring data from the device **10** to the control system **220**.

When the method **600** begins, the processor **435** is in the wait state. In block **605**, the processor **435** determines a predetermined transmission interval has lapsed since a transmission was last sent by the device **10** to an external device (e.g., e.g., the patient desktop computer **335**, the patient cellular telephone **350**, the patient portable computer **355**, the Internet gateway device **365**, and the like). As discussed above, the external device is configured to transfer the data sent to it by the device **10** to the control system **220**.

In block **615**, the processor **435** retrieves the calculated values, the accelerometer value(s), and optionally the data obtained from the oximeter **420** and/or the heart rate sensor **415** stored in the memory **410** (see FIG. **4**) in blocks **570** and **580** of the method **500** (see FIG. **5**). In block **620**, the information retrieved is formatted for transmission (e.g., placed in transmission packets) and subsequently transferred to the external device in block **630**.

In decision block **635**, the processor **435** determines whether a transfer confirmation has been received from the external device. The decision in decision block **635** is "YES" when the device **10** has received a transfer confirmation from the external device in response to the transmission sent in block **630**. Otherwise, the decision in decision block **635** is "NO" when the device **10** has not received a transfer confirmation from the external device in response to the transmission sent in block **630**. Optionally, even if a transfer confirmation is received, the decision in decision block **635** may nevertheless be "NO," if the processor **435** determines that a problem occurred when the calculated values were transmitted in block **630**.

When the decision in decision block **635** is "YES," the method **600** terminates.

When the decision in decision block **635** is "NO," in block **640**, the processor **435** stores bad send data in the memory **410** for analysis. Then, the processor **435** returns to block **615**.

FIG. **6**B is a flow diagram of a method **650** performed by the processor **435**. The method **650** is performed when the device **10** receives data from the control system **220**. The device **10** may receive data from the control system **220** following the successful transfer of data (e.g., the calculated values, the accelerometer value(s), and optionally the data obtained from the oximeter **420** and/or the heart rate sensor **415**) to the control system **220**.

In first block **652**, the processor **435** waits to receive a transmission from the control system **220**.

In block **655**, the device **10** receives data, such as a setting value, constant value, and the like, from the control system **220**.

In block **660**, the processor **435** determines whether a problem occurred when the data was received from the control system **220**. For example, if too much time has elapsed since data was last received from the control system **220**, the processor **435** may determine a problem occurred. The decision in decision block **660** is "YES," when the processor **435** determines a problem has occurred. On the other hand, the decision in decision block **660** is "NO," when the processor **435** determines a problem has not occurred.

When the decision in decision block **660** is "YES," in block **665**, the processor **435** stores data related to the problem (e.g., increments a bad receive count value). Then, the processor **435** returns to block **652** to wait for additional transmissions from the control system **220**. By way of an example, the control system **220** may retransmit data to the device **10** if the control system **220** determines the data was not received by the device.

When the decision in decision block **660** is "NO," in optional block **670**, the processor **435** may send a receipt confirmation to the control system **220** confirming the data was received. Then, in block **680**, the device **10** stores the data received and the method **650** terminates.

FIG. **7** is a flow diagram of a method **700** of receiving the calculated values at the control system **200**. By way of a non-limiting example, the method **700** will be described as being performed by the database server **370** (see FIG. **3**).

In first block **705**, the database server **370** waits to receive a transmission from the device **10** (via one of the external devices). In decision block **707**, the database server **370** determines whether it has been waiting too long (e.g., longer than a predetermined amount of time) indicating there may be a problem with the device **10** or, in embodiments of the device **10** configured to communicate wirelessly, that the device **10** was positioned outside a radio coverage area. The decision in decision block **707** is "YES" when the database server **370** has been waiting too long for a transmission from the device **10**. On the other hand, the decision in decision block **707** is "NO" when the database server **370** has not been waiting too long for a transmission from the device **10**.

When the decision in decision block **707** is "NO," the database server **370** continues to wait and in block **710**, receives the transmission (including the calculated values, accelerometer value(s), and optionally the data obtained from the oximeter **420** and/or the heart rate sensor **415**) from the device **10**.

In decision block **715**, the database server **370** determines whether a problem occurred when the calculated values, accelerometer value(s), and optionally the data obtained from the oximeter **420** and/or the heart rate sensor **415** were received from the device **10**. For example, the calculated value for the detector "D**1**" may be compared to a valid range stored in the database server **370**. If the calculated value for the detector "D**1**" is outside the valid range, the database server **370** may determine a problem occurred. The decision in decision block **715** is "YES," when the database server **370** determines a problem has occurred. On the other hand, the decision in decision block **715** is "NO," when the database server **370** determines a problem has not occurred.

When the decision in decision block **715** is "YES," in block **720**, the database server **370** stores data related to the problem (e.g., increments a bad receive count value). Then, the database server **370** returns to block **705** to wait for additional transmissions from the device **10**. By way of an example, the device **10** may retransmit data to the control system **220** if the device **10** determines the formatted data was not received by the control system.

When the decision in decision block **715** is "NO," in optional block **730**, the database server **370** may send a receipt confirmation to the device **10** confirming the calculated values, accelerometer value(s), and optionally the data obtained from the oximeter **420** and/or the heart rate sensor **415** were received. In block **740**, the database server **370** stores the calculated values, accelerometer value(s), and optionally the data obtained from the oximeter **420** and/or the heart rate sensor **415** received. Then, the method **700** terminates. The calculated values, accelerometer value(s), and optionally the data obtained from the oximeter **420** and/or the heart rate sensor **415** may be stored in a patient record associated with the device **10**. By way of a non-limiting example, the transmission received by the control system **220** may include a device identifier associated with the device **10** that may be used to identify the patient record associated with the device.

When the decision in decision block **707** is "YES," the database server **370** has been waiting too long for a transmission from the device **10** and in block **742**, sends a notification indicating a problem has occurred to the device **10**, the patient desktop computer **335**, the patient cellular telephone **350**, and/or the patient portable computer **355** to be reviewed by the patient **230**. In optional block **745**, the database server **370** may send a notification to the support network **210** and/or the healthcare system **205** indicating a problem has occurred. Then, the method **700** terminates.

Referring to FIGS. **13** and **17**, as will be explained in greater detail below, the device **10** includes a flexible but inelastic strap **1310** having a first end portion **1312** opposite a second end portion **1314**. An optical gradient **1545** is coupled to the first end portion **1312**. An electronics enclosure **1335** is coupled to the second end portion **1314** by a guide portion **1315** of a frame member **1337** positioned about the periphery of the electronics enclosure **1335**.

The electronics enclosure **1335** includes a sensor portion **1515**. The emitter "E**1**" and detector "D**1**" of the sensor **450**, the emitter "E**2**" and detector "D**2**" of the sensor **455**, and the emitter "E**3**" and detector "D**3**" of the sensor **460** are positioned on the sensor portion **1515** of the electronics enclosure **1335**.

The first end portion **1312** is coupled to the electronics enclosure **1335** by a tensioning member **1320**. When the first end portion **1312** is coupled to the electronics enclosure **1335**, the sensor portion **1515** extends under the first end portion **1312** of the strap **1310** and the emitters "E**1**," "E**2**," and "E**3**" and detectors "D**1**," "D**2**," and "D**3**" face toward the optical gradient **1545** coupled to the first end portion **1312** of the strap **1310**.

The tensioning member **1320** is elastic and may be stretched to accommodate the patient's limb **11**. Referring to FIG. **10**B, when the strap **1310** is wrapped snuggly around a cylinder, edges **1316** and **1318** the first and second end portions **1312** and **1314**, respectively, will be substantially parallel with one another. However, when the strap **1310** is wrapped snuggly about a tapered object (e.g., a wrist, an ankle, and the like), the strap **1310** will follow the tapered surface of the object and the edges **1316** and **1318** the first and second end portions **1312** and **1314**, respectively, will not be substantially parallel with one another. In other words, an angle "θ" is defined between the edges **1316** and **1318** when the strap **1310** is wrapped snuggly about a tapered object (e.g., a wrist, an ankle, and the like).

As mentioned above, the sensors **450**, **455**, and **460** are adjacent the optical gradient **1545**. The sensors **450**, **455**, and **460** are positioned such that light emitted by the emitters "E**1**," "E**2**," and "E**3**" is reflected by the optical gradient and detected by the detectors "D**1**," "D**2**," and "D**3**," respectively. Referring to FIG. **9**, the exemplary optical gradient **1545** illustrated includes a first gradient portion "G**1**," a second gradient portion "G**2**," and a solid portion "GS" positioned between the first and second gradient portions. In the embodiment illustrated, reflectivity of the first and second gradient portions "G**1**" and "G**2**" changes linearly along a gradient direction (indicated by an arrow "GD"). However, reflectivity of the solid portion "GS" does not change along the gradient direction (indicated by an arrow "GD"). In the embodiment illustrated, the reflectivity of the first and second gradient portions "G**1**" and "G**2**" is greater toward the right hand side than toward the left hand side of FIG. **9**. Further, the first and second gradient portions "G**1**" and "G**2**" are aligned along a transverse direction (indicated by an arrow "TD") such that along the transverse direction the reflectivity of the first gradient portion "G**1**" is substantially identical to the reflectivity of the second gradient portion "G**2**." Thus, for each location along the gradient direction (indicated by an arrow "GD"), the first gradient portion "G**1**" has a reflectivity substantially identical (or corresponding) to the reflectivity of the second gradient portion "G**2**."

The sensor **450** is positioned adjacent to the first gradient portion "G**1**," the sensor **455** is positioned adjacent to the solid portion "GS," and the sensor **460** is positioned adjacent to the second gradient portion "G**2**." Thus, the calculated value for sensor **455** should not vary based on the positioning of the sensor **455** relative to the solid portion "GS" along the gradient direction (indicated by the arrow "GD"). However, the calculated values for the sensors **450** and **460** will vary based on the positioning of the sensors **450** and **460** relative to the first and second gradient portions "G**1**" and "G**2**," respectively, along the gradient direction (indicated by the arrow "GD"). As will be explained in more detail below, the calculated value for the sensor **455** may be used to verify the alignment of the sensors **450**, **455**, and **460** with the optical gradient **1545**, and the calculated values for the sensors **450** and **460** may be used to determine the position of the device **10** on the patient's limb **11** and a circumference measurement of the patient's limb.

FIG. **8**A is a flow diagram of a method **750** of creating a model of the patient's limb **11** for use by a method **800** describe below and illustrated in FIG. **8**B. The method **750** may be performed by the device **10**, the control system **220**, and/or a combination thereof. The model correlates positions along the longitudinal axis of the limb **11** with a measure of the distance around the limb **11**. The calculated values received by the database server **370** indicate how much radiation was detected by the detectors "D**1**," "D**2**," and "D**3**." As explained above, the amount of radiation detected by the detectors "D**1**," "D**2**," and "D**3**" varies based on where the detectors are positioned relative to the optical gradient **1545** (see FIG. **9**). Where the detectors "D**1**," "D**2**," and "D**3**" are positioned relative to the optical gradient **1545** varies with the distance around the patient's limb **11** (or the limb's circumference) in the location on the limb whereat the device **10** is positioned. Therefore, the calculated values may be used as the measure the distance around the patient's limb **11** in the model. In such embodiments, the database server **370** may determine changes in the distance around the patient's limb **11** using the calculated values without actually determining the distance around the patient's limb **11**. Alternatively, the calculated values (which measure an amount of radiation) may be used to obtain distance measurements. In such embodiments, the distance measurements obtained from the calculated values may be used as the measure the distance around the patient's limb **11** in the model. By way of a non-limiting example, the calculated values may be converted into distance measurements by correlating the amount of radiation detected with a circumference measurement.

For ease of illustration, the distance measurements (or circumference measurements) obtained from the calculated values will be described as being the measure the distance around the patient's limb **11** used in the model. However, this is not a requirement and embodiments in which a different measure of the circumference of the limb **11** is used to generate the model are also within the scope of the present teachings.

FIG. **12** is a graph in which the x-axis corresponds to the longitudinal axis of the limb **11** and the y-axis corresponds to the distance around the around the patient's limb **11**. The limb **11** (see FIG. **1**) may be modeled as a three-dimensional surface (e.g. a hyperboloid of one sheet) that is symmetric about a longitudinally axis (e.g., the x-axis). Such a model may be created by rotating a contoured line (e.g., a solid contoured line "L**1**") spaced apart from and extending along the longitudinally axis about the longitudinally axis. In FIG. **12**, a dashed line "L**2**" illustrates the contoured line "L**1**" rotated about the x-axis. The area between the contoured line "L**1**" and the dashed line "L**2**" represents a cross-sectional area (through the longitudinal axis) of a portion of the limb **11**.

The contoured line "L**1**" models the circumference of the limb **11** at a range of locations along the longitudinal axis of the limb. The contoured line "L**1**" may be defined by a predefined mathematical equation and one or more circumference measurements (illustrated as points "A**1**" to "A**8**") collected from the patient's limb **11**. The predefined mathematical equation may be fit to the patient's limb **11** using the one or more circumference measurements (illustrated as points "A**1**" to "A**8**") collected from the limb **11**. In other words, curve fitting techniques may be used to derive the contoured line "L**1**" by modifying a mathematical equation based on circumference measurements collected from the limb **11**.

In FIG. **12**, the contoured line "L**1**" used to model the patient's limb **11** is a parabola. In FIG. **12**, a minimum circumference "MC-**1**" of the model of the limb **11** is positioned on the y-axis above an intersection of the x-axis and the y-axis. For ease of illustration, in FIG. **12**, the right-hand side of the x-axis is extending toward an extremity (e.g., a hand or a foot) and the left-hand side of the x-axis is extending away from the extremity. At the wrist, the arm typically narrows (or has a smaller circumference). Similarly, at the ankle, the leg typically narrows (or has a smaller circumference). Therefore, the minimum circumference "MC-**1**" may be used as the circumference measurement of the limb **11**.

Turning to FIG. **8**A, in first block **760**, circumference measurements (e.g., those illustrated as points "A**1**" to "A**8**") are collected from the patient's limb **11**. In block **760**, a setup operation may be performed by the patient **230**, the support person **330**, the caregiver **332**, a combination thereof, and the like, in which the device **10** is positioned at different locations along the patient's limb **11**. At each location, the device **10** is used to capture at least one circumference measurement. During the setup operation, the device **10** may be positioned in predetermined locations so the control system **220** can readily correlate each of the circumference measurements with a position on the patient's limb **11**. The patient **230**, the support person **330**, and/or the caregiver **332** may inform (e.g., via the website **217**) the control system **220** that the setup operation is being performed. Alternatively, the control system **220** may instruct the patient **230**, the support person **330**, and/or the caregiver **332** to perform the setup operation (e.g., via the website **217**).

During the setup operation the method **500** illustrated in FIG. **5** may be used to collect calculated values for each location in which the device **10** is positioned. When collecting calculated values, in block **505**, the method **500** uses the predetermined measurement interval. However, during the setup operation, a different interval (e.g., a shorter interval) may be used in block **505**. Further, the device **10** may include an indicator (not shown) that may indicate when calculated values have been collected for a particular location so that the person positioning the device on the limb **10** may reposition the device **10** in a next position. The indicator (not shown) may include a speaker, a light, and the like. In such embodiments, the device **10** may produce a sound and/or illuminate a light each time the method **500** terminates during the performance of the setup operation. Alternatively, the device **10** may include a manually operable switch (e.g., a button) that the person positioning the

device **10** may activate to indicate the device has been repositioned and the method **500** should be performed by the processor **435** (see FIG. **4**).

The method **600** (see FIG. **6**) is performed one or more times by the processor **435** (see FIG. **4**) to transfer the calculated values obtained during the setup operation to the database server **370** (see FIG. **3**). The method **700** (see FIG. **7**) is performed one or more times by the database server **370** (see FIG. **3**) to receive the calculated values obtained during the setup operation from the processor **435** (see FIG. **4**).

After the database server **370** (see FIG. **3**) has received the calculated values obtained during the setup operation from the processor **435** (see FIG. **4**), in block **770**, the database server **370** performs curve fitting techniques to generate a model of the patient's limb **11** based on the circumference measurements obtained from the calculated values. As explained above, the calculated values may be converted or otherwise used to obtain circumference measurements. Further, in some embodiments, the calculated values may be used as the circumference measurements.

Those of ordinary skill in the art appreciate that the device **10** illustrated does not collect a measurement of the position of the device **10** along the limb **11**. In other words, the device **10** collects the y-coordinate of the points "A**1**" to "A**8**" but not the x-coordinate. As mentioned above, during the setup operation, the device **10** may be positioned in predetermined locations so the control system **220** can readily correlate each of the circumference measurements with a position on the patient's limb **11**.

By way of another example, each pair of circumference measurements (collected using the sensors **450** and **460** illustrated in FIG. **4**) may be used to determine the position of the device **10** on the patient's limb **11** (e.g. the x-coordinates of the points "A**1**" to "A**8**") for the purposes of generating the model. In FIG. **12**, the pairs include a first pair of circumference measurements (illustrated as points "A**1**" and "A**2**"), a second pair of circumference measurements (illustrated as points "A**3**" and "A**4**"), a third pair of circumference measurements (illustrated as points "A**5**" and "A**6**"), and a fourth pair of circumference measurements (illustrated as points "A**7**" and "A**8**").

The circumference measurements in each of the pairs are spaced apart by a predetermined distance "PD." The predetermined distance "PD" may be substantially equal to a distance (e.g., about 20 millimeters) between the sensor **450** and the sensor **460**. When the pairs of circumference measurements are collected, the strap **1310** is allowed to follow the surface of the patient's limb **11** and minor measurement deviations caused by non-planar aspects of the limb **11** may be ignored. Each of the pairs of circumference measurements may be used to determine an amount of taper in the patient's limb **11** between the locations whereat the measurements were taken. By way of an example, a line "T**1**" illustrates an amount of taper between the circumference measurements (illustrated as points "A**7**" and "A**8**") of the fourth pair.

Further, if the orientation of the device **10** is known, the direction of the taper may be used to determine whether a pair of circumference measurements is positioned at or near the minimum circumference "MC-**1**," toward the extremity relative to the minimum circumference "MC-**1**," or away from the extremity relative to the minimum circumference "MC-**1**."

The orientation of the device **10** may be determined by performing orientation signal processing on the accelerometer value(s) transferred with the calculated values. By way of a non-limiting example, an accelerometer with three orthogonal sensing elements detects static deflections in each of the sensing elements that can be used to determine gravitation direction and thus device orientation. Such orientation signal processing is known in the art and will not be described in detail. If at the time of a measurement, the accelerometer value(s) indicate the device **10** is horizontal (i.e., the acceleration of gravity is substantially orthogonal to the longitudinal axis of the limb **11**), a previously determined orientation of the device **10** may be used. For example, the most recently determined non-horizontal orientation may be used.

In alternate embodiments, instead of pairs of circumference measurements spaced apart by the predetermined distance "PD," a single circumference measurement (e.g., the point "A**7**" in FIG. **12**) and the angle "θ" (see FIGS. **10**A and **10**B) may be used to define the contoured line "L**1**." The angle "θ" may serve the same purpose as the second circumferential measurement of each of the pairs of circumferential measurements discussed above. Specifically, the angle "θ" may be used to determine an amount of taper in the patient's limb **11** whereat the circumference measurement was taken. Using multiple circumference measurements and angle "θ" for each circumference measurement, the contoured line "L**1**" (e.g., a parabolic curved line) may be defined using curve fitting techniques.

In block **771**, the database server **370** uses the circumference measurements collected during the setup operation and/or an update operation (discussed below) to generate a lookup table (not shown). Returning to FIG. **12**, a difference between the circumference measurements of each of the pairs (referred to as a "circumference differential value") may be correlated with a position along the longitudinal axis of the limb **11**. For example, the difference between the y-coordinates of the first pair of circumference measurements (plotted as points "A**1**" and "A**2**") is larger than the difference between the y-coordinates of the second pair of circumference measurements (plotted as points "A**3**" and "A**4**"), indicating the first pair is farther from the minimum circumference "MC-**1**" than the second pair.

The lookup table may list the following values for each pair of circumference measurements:

1) at least one of the circumference measurements of the pair of circumference measurements;
2) the circumference differential value; and
3) the minimum circumference "MC-**1**."

As will be explained below, the lookup table may be used by the database server **370** to determine whether the circumference of the limb **11** has changed.

In block **772**, the database server **370** waits to receive new circumference measurements from the device **10**. By way of a non-limiting example, the database server **370** may wait for a predetermined interval.

In decision block **775**, the database server **370** determines whether new circumference measurements have been received. The decision in decision block **775** is "YES" when new circumference measurements have been received. On the other hand, the decision in decision block **775** is "NO" when new circumference measurements have not been received.

When the decision in decision block **775** is "NO," the method **750** terminates.

When the decision in decision block **775** is "YES," in decision block **780**, the database server **370** determines whether to update the model. The decision in decision block **780** is "YES" when the database server **370** decides to

update the model. On the other hand, the decision in decision block **780** is "NO" when the database server **370** decides not to update the model.

When the decision in decision block **780** is "NO," the database server **370** returns to block **772** to wait for new circumference measurements.

When the decision in decision block **780** is "YES," new circumference measurements are used to update or modify the model. The new circumference measurements may be those accumulated as the device **10** is worn by the patient **230** (e.g., the new circumference measurements received before decision block **775**) and/or new circumference measurements collected during an update operation.

Further, other information, such as patient height and weight may be considered and used to modify the model. For example, if the patient **230** has gained weight other than by the retention of fluids, an increase in limb circumference may merely be the result of the weight gain. Therefore, the model (e.g., equation defining the contoured line "L**1**") may be updated to reflect the change in limb size.

In decision block **790**, the database server **370** determines whether to perform the update operation, which may be substantially similar to the setup operation. The decision in decision block **790** is "YES" when the database server **370** decides to perform the update operation. On the other hand, the decision in decision block **790** is "NO" when the database server **370** decides not to perform the update operation.

The setup or update operations may be performed when the length of the strap **1310** is adjusted (e.g., tightened or loosened). Further, the setup or update operations may be performed when the strap **1310** is replaced because manufacturing variations may exist in the reflective qualities of the optical gradient **1545** or strap **1310**. This setup or update operations may be performed by the control system **220** automatically. Further, a user (e.g., the patient **230**, the support person **330**, the caregiver **332**, and the like) may initiate the performance of the setup or update operations (e.g., in response to a recalibration notice).

When the decision in decision block **790** is "YES," the block **760** is performed to collect the new circumference measurements. Then, in block **770**, the database server **370** regenerates the model using the circumference measurements collected during the setup operation, the new circumference measurements collected during the update operation, and optionally, the new circumference measurements collected (before decision block **775**) as the device **10** was worn by the patient **230**.

When the decision in decision block **790** is "NO," in block **770**, the database server **370** regenerates the model using the circumference measurements collected during the setup operation as well as the new circumference measurements.

While the contoured line "L**1**" has been described as being a parabola, instead, the contoured line "L**1**" may be V-shaped. In such an implementation, the wrist or ankle is modeled as two cones axially aligned and merged together near each of their points. However, each of the cones has a linear taper and constant surface angle with respect to the axis of the cone. In contrast, a limb, particularly near the wrist or ankle, has a curved and somewhat parabolic shape. Thus, it may be desirable for the contoured line "L**1**" to have a rate of taper change, or apparent surface angle change that is not constant. In particular, it may be desirable for the rate of taper change to lessen near the minimum circumference "MC-**1**" and increase progressively outwardly from the minimum circumference as occurs in a parabola.

By way of yet another non-limiting example, the model of the three-dimensional surface of the limb **11** may be constructed using anatomical data. For example, the model may be created by scanning a representative human limb or combining multiple scans of limbs to create a composite model. Multiple models may be created for different genders, ages, heights, weights, a combination thereof, and the like. Further, a model may be created for each patient by scanning the limb **11** of the patient **230**.

In FIG. **12**, the contoured line "L**1**" is symmetric about the y-axis. Thus, the contoured line "L**1**" indicates the rate of change in the surface angle of the limb **11** is the same at locations equidistant from the minimum circumference "MC-**1**" along the longitudinal axis of the limb **11**. However, this may not be the case. Because the rate of change of the surface angle of the patient's limb **11** is likely to be different and nonsymmetrical along the longitudinal axis of the limb **11** from the minimum circumference "MC-**1**" toward the direction toward the extremity (e.g., foot or hand) than in the opposite direction from the minimum circumference "MC-**1**," different mathematical equations or a different model may be used to model these portions of the limb **11**. As mentioned above, the accelerometer value(s) may be used to determine the orientation of the device **10** so that whether the device **10** is above or below the minimum circumference "MC-**1**" may be determined.

FIG. **8**B is a flow diagram of the method **800** of analyzing the calculated values and accelerometer value(s) (and optionally the data obtained from the oximeter **420** and/or the heart rate sensor **415**) optionally transferred to the control system **220** by the device **10**. By way of a non-limiting example, the method **800** will be described as being performed by the database server **370** (see FIG. **3**). However, in alternate embodiments, the method **800** may be performed by the device **10**, the control system **220**, and/or a combination thereof. The method **800** may be performed immediately after block **740** in the method **700**. Alternatively, the method **800** may be performed after two or more transmissions are received from the device **10**. By way of yet another non-limiting example, the method **800** may be performed at predetermined intervals.

For ease of illustration, the method **800** will be described with respect to the circumference measurements plotted as points "P**1**" and "P**2**" in FIG. **12**. However, as is apparent to those of ordinary skill in the art, the method **800** may be performed with respect to more than a pair of circumference measurements.

In first block **810**, the database server **370** determines an orientation of the device **10** when the "lit" analog signals used to determine the calculated values from which the circumference measurements plotted as the points "P**1**" and "P**2**" in FIG. **12** were collected. In block **810**, the database server **370** performs orientation signal processing on the accelerometer value(s) transferred with the calculated values to determine the orientation of the device **10** on the limb **11**. By way of a non-limiting example, an accelerometer with three orthogonal sensing elements detects static deflections in each of the sensing elements that may be used to determine gravitation direction and thus device orientation. Such orientation signal processing is known in the art and will not be described in detail. The database server **370** may store the orientation of the device **10**.

In optional decision block **820**, the database server **370** may determine whether the sensors **450**, **455**, and **460** were properly aligned with the optical gradient **1545**. The calculated value for the sensor **455** may be used to verify the alignment of the emitter "E**2**" with the optical gradient **1545**.

For example, if the calculated value is within a predetermined range expected for the solid portion "GS" of the optical gradient **1545**, the database server **370** determines the sensors **450**, **455**, and **460** were properly aligned with the optical gradient **1545**. Otherwise, if the calculated value is not within the predetermined range expected for the solid portion "GS" of the optical gradient **1545**, the database server **370** determines the sensors **450**, **455**, and **460** were improperly aligned.

The decision in optional decision block **820** is "YES" when the database server **370** determines the sensors **450**, **455**, and **460** were properly aligned with the optical gradient **1545**. On the other hand, the decision in optional decision block **820** is "NO" when the database server **370** determines the sensors **450**, **455**, and **460** were improperly aligned with the optical gradient **1545**.

When the decision in optional decision block **820** is "NO," in optional block **825**, the database server **370** may indicate a misalignment occurred. Then, the method **800** terminates having failed to determine a final circumference value (or edema measure).

When the decision in optional decision block **820** is "YES," or the optional decision block **820** is omitted, in block **835**, the database server **370** calculates a circumference differential value for the circumference measurements plotted as the points "P**1**" and "P**2**" in FIG. **12**. As explained above, to calculate the circumference differential value, the database server **370** may calculate a first circumference measure for the sensor **450** based on the calculated value for the sensor **450** and a second circumference measure for the sensor **460** based on the calculated value for the sensor **460**. For ease of illustration, the device **10** will be described as being in the orientation illustrated in FIGS. **13** and **17**. However, this is not a requirement. When the device **10** is in this orientation, the sensor **460** is nearer an extremity (e.g., a hand or a foot) and is positioned below the sensor **450**, which is farther away from the extremity. Thus, the sensor **450** may be characterized as being an upper sensor and the sensor **460** may be characterized as being a lower sensor. However, as is appreciated by those of ordinary skill in the art, the assignment of upper and lower are purely arbitrary and vary based upon the position of the patient's limb. By way of a non-limiting example, the circumference differential value may be calculated by subtracting the first circumference measure for the (upper) sensor **450** from the second circumference measure for the (lower) sensor **460**.

If the circumference differential value is approximately zero, the sensors **450** and **460** are adjacent portions of the optical gradient **1545** having substantially equivalent reflectivity. Because the first and second gradient portions "G**1**" and "G**2**" are substantially aligned with one another, this means the sensors **450** and **460** are adjacent corresponding portions of the first and second gradient portions "G**1**" and "G**2**." The device **10** is illustrated in this configuration in FIG. **10**B. This may indicate the device **10** is positioned approximately at the patient's wrist or ankle.

On the other hand, if the circumference differential value is greater than or less than zero, the sensors **450** and **460** are not adjacent corresponding portions of the first and second gradient portions "G**1**" and "G**2**." As will be described in greater detail below, the position of the sensors **450**, **455**, and **460** relative to the optical gradient **1545** varies with the circumference of the patient's limb **11**. Further, the position of the sensors **450**, **455**, and **460** relative to the optical gradient **1545** along the transverse direction (indicated by the arrow "TD") may vary based upon the location of the device **10** on the patient's limb **11**.

If the circumference differential value is greater than zero, the device **10** may be positioned above the patient's wrist or ankle. The device **10** is illustrated in this configuration in FIG. **10**A. On the other hand, if the circumference differential value is less than zero, the device **10** may be positioned below the patient's wrist or ankle. The device **10** is illustrated in this configuration in FIG. **10**C.

In decision block **840**, the database server **370** determines whether the circumference differential value is too large, indicating improper placement of the device **10**. By way of a non-limiting example, the database server **370** may determine the circumference differential value is too large if the circumference differential value is greater than a predetermined threshold value. The decision in decision block **840** is "YES" when the database server **370** determines the circumference differential value is too large. On the other hand, the decision in decision block **840** is "NO" when the database server **370** determines the circumference differential value is not too large.

When the decision in decision block **840** is "YES," in optional block **845**, the database server **370** sends a message to the patient **230** to adjust the position of the device **10**. Further, in optional block **845**, the database server **370** may remove the calculated values from the patient record. Then, the method **800** terminates.

Because the circumference of the limb **11** varies along its longitudinal axis, to compare successive circumference measurements to one another directly, the circumference measurements must have been collected from nearly identical locations along the longitudinal axis of the limb **11**. Because the device **10** may move along the longitudinal axis of the limb **11**, it may not be possible to compare successive circumference measurements directly. Further, the patient **230** may inadvertently position the device **10** in different locations along the patient's limb between circumference measurements, which could contribute to measurement errors. However, as explained above, the model (e.g., the contoured line "L**1**") may be used to obtain the minimum circumference "MC-**1**" (or an estimate thereof) for the limb **11**. The minimum circumference values obtained from successive circumference measurements may be compared directly because they are believed to be from the same location on the limb **11**.

When the decision in decision block **840** is "NO," in block **850**, the database server **370** determines a minimum circumference "MC-**3**" for the circumference measurements plotted as the points "P**1**" and "P**2**" in FIG. **12** and whether the minimum circumference "MC-**3**" indicates the size of the limb **11** has changed. As mentioned above, the database server **370** may create a lookup table using the pairs of circumference measurements used to create the model.

The database server **370** may use the lookup table to determine whether the minimum circumference "MC-**3**" and whether the circumference of the limb **11** has changed. For example, the database server **370** may determine the circumference of the limb **11** has not changed if the newly measured pair of circumference measurements (plotted as the points "P**1**" and "P**2**" in FIG. **12**) includes a circumference measurement corresponding to the circumference measurement stored in the lookup table for a previously collected pair of circumference measurements, and the circumference differential value of the new pair of circumference measurements matches the circumference differential value stored for the same previously collected pair of circumference measurements. When this is the case, the minimum circumference "MC-**1**" associated with the previ-

ously collected pair of circumference measurements may be used as the minimum circumference "MC-3" for the new pair.

Similarly, the database server **370** may determine the circumference of the limb **11** has not changed if the newly measured pair of circumference measurements (plotted as the points "P1" and "P2" in FIG. **12**) includes a circumference measurement between the circumference measurements stored in the lookup table for a first previously collected pair of circumference measurements and a second previously collected pair of circumference measurements, and the circumference differential value of the new pair of circumference measurements is between the circumference differential values stored for the first and second previously collected pairs of circumference measurements. When this is the case, the minimum circumference "MC-1" associated with the previously collected pair of circumference measurements may be used as the minimum circumference "MC-3" for the new pair. The position of the new pair on the contoured line "L1" may be determined using interpolation (e.g., linear interpolation) between the first and second previously collected pairs of circumference measurements.

However, the database server **370** may determine the circumference of the limb **11** has changed if the newly measured pair of circumference measurements (plotted as the points "P1" and "P2" in FIG. **12**) includes a circumference measurement corresponding to the circumference measurement stored in the lookup table for a previously collected pair of circumference measurements, but the circumference differential value of the new pair of circumference measurements does not match the difference value stored for the same previously collected pair of circumference measurements. Similarly, the database server **370** may determine the circumference of the limb **11** has changed if the newly measured pair of circumference measurements includes a circumference measurement between the circumference measurements stored in the lookup table for a first previously collected pair of circumference measurements and a second previously collected pair of circumference measurements, but the circumference differential value of the new pair of circumference measurements is not between the circumference differential values stored for the first and second previously collected pairs of circumference measurements.

Referring to FIG. **12**, if the limb **11** has swelled but its shape has remained substantially unchanged, the swollen limb may be modeled by a contoured line "L3," which has the same shape as the contoured line "L1," but is shifted upwardly on the y-axis relative to the contoured line "L1." In this example, the point "P1" is aligned vertically with the point "A7" and the point "P2" is aligned vertically with the point "A8." Therefore, the circumference differential value of the new pair of circumference measurements (plotted as the points "P1" and "P2") is the same as the circumference differential value stored in the lookup table for the previously collected pair of circumference measurements (plotted as the points "A7" and "A8"). However, a first circumference measurement (plotted as the point "P1") of the new pair is larger than the corresponding first circumference measurement (plotted as the point "A7") of the previously collected pair. Similarly, a second circumference measurement (plotted as the point "P2") of the new pair is larger than the corresponding second circumference measurement (plotted as the point "A8") of the previously collected pair. Thus, no matter which of the circumference measurements of the previously collected pair are stored in the lookup table, the lookup table will indicate the limb **11** has swollen when corresponding circumference measurements of the new and previously collected pairs are compared to one another.

Referring to FIG. **12**, if swelling in the limb **11** has reduced but its shape has remained substantially unchanged, the limb may be modeled by a contoured line having the same shape as the contoured line "L1," but shifted downwardly on the y-axis relative to the contoured line "L1." The circumference differential value of a new pair of circumference measurements will be the same as the circumference differential value stored in the lookup table for a previously collected pair of circumference measurements. However, a first circumference measurement of the new pair will be smaller than the corresponding first circumference measurement of the previously collected pair. Similarly, a second circumference measurement of the new pair will be smaller than the corresponding second circumference measurement of the previously collected pair. Thus, no matter which of the circumference measurements of the previously collected pair are stored in the lookup table, the lookup table will indicate swelling in the limb **11** has reduced when corresponding circumference measurements of the new and previously collected pairs are compared to one another.

When the database server **370** determines the size of the limb **11** has changed, the database server **370** generates a contoured line (e.g., the contoured line "L3"), and uses the contoured line to determine the minimum circumference (e.g., the minimum circumference "MC-3") of the limb **11**.

In block **852**, the database server **370** compares the previously obtained minimum circumference "MC-1" to the newly measured minimum circumference (e.g., the minimum circumference "MC-3").

In decision block **854**, the database server **370** determines whether the newly measured minimum circumference (e.g., the minimum circumference "MC-3") is larger than the previously obtained minimum circumference "MC-1," indicating the limb **11** has swollen. The decision in decision block **854** is "YES" when the newly measured minimum circumference (e.g., the minimum circumference "MC-3") is larger than the previously obtained minimum circumference "MC-1." On the other hand, the decision in decision block **854** is "NO" when the newly measured minimum circumference (e.g., the minimum circumference "MC-3") is not larger than the previously obtained minimum circumference "MC-1."

When the decision in decision block **854** is "NO," the database server **370** advances to block **885**.

When the decision in decision block **854** is "YES," in block **875**, the database server **370** analyzes one or more triggers to determine whether any have been satisfied such that a message is be sent to the patient **230** (e.g., the message **225** illustrated in FIG. **2**), the support person **330**, and/or the caregiver **332**. For example, a trigger may have been entered into the website **217** indicating that if the limb **11** swells by more than a trigger threshold value, the message **225** (see FIG. **2**) is to be sent to the patient **230**. In block **875**, the database server **370** determines by how much the limb **11** has swelled and compares that amount to the trigger threshold value.

By way of example, in block **875**, the database server **370** may determine an amount of change and/or a rate of change. In block **875**, the database server **370** may try to identify a trend indicative of a problem. For example, if the minimum circumference values appear to be increasing, the patient **230** may be experiencing a medical problem. In block **875**, the database server **370** may determine an amount by which edema in the limb **11** has changed.

In decision block **880**, the database server **370** determines whether one or more triggers are satisfied indicating a problem. The decision in decision block **880** is "YES" when the database server **370** determines one or more triggers are satisfied. On the other hand, the decision in decision block **880** is "NO" when the database server **370** determines none of the triggers are satisfied.

When the decision in decision block **880** is "NO," in optional block **885**, the database server **370** may send a notification indicating no problem has been detected to the device **10**, the patient desktop computer **335**, the patient cellular telephone **350**, the patient portable computer **355**, and the like to be viewed by patient **230**. The notification may be viewable on the website **217** (see FIG. **2**). Optionally, the database server **370** may send a notification indicating no problem has been detected to the computing device **310** to be viewed by the support person **330** and/or to the computing device **315** to be viewed by the caregiver **332**. Any such notifications may be viewable on the website **217** (see FIG. **2**). Then, the method **800** terminates.

When the decision in decision block **880** is "YES," in block **890**, the database server **370** may send a notification indicating a problem has been detected to the device **10**, the patient desktop computer **335**, the patient cellular telephone **350**, the patient portable computer **355**, and the like to be viewed by patient **230**. The notification may be viewable on the website **217** (see FIG. **2**). Optionally, the database server **370** may send a notification indicating a problem has been detected to the computing device **310** to be viewed by the support person **330** and/or to the computing device **315** to be viewed by the caregiver **332**. Any such notifications may be viewable on the website **217** (see FIG. **2**).

Instructions may be associated with the trigger and included in the message sent to the patient **230**, the support person **330**, and/or the caregiver **332**. The instructions may include a predefined treatment plan. Then, the method **800** terminates.

FIG. **11** is a flow diagram of a method **1100** of processing triggers specified for sensors other than the sensors **450**, **455**, and **460**. The method **1100** may be performed by the device **10**, the control system **220**, and/or a combination thereof. For ease of illustration, the method **1100** will be described as being performed by the database serve **370**. As mentioned above, the patient **230**, the support person **330**, and/or the caregiver **332** may use the website **217** to specify trigger conditions (e.g., threshold values) that trigger messages to the patient **230**, the support person **330**, and/or the caregiver **332**. The method **1100** may be used with the accelerometer values(s) obtained from the accelerometer **405**, oxygen amounts obtained from the oximeter **420**, and/or heart rate values obtained from the heart rate sensor **415**. Further, the method **1100** may be used with the calculated values obtained from the sensors **450**, **455**, and **460** combined with the data from one or more of the other sensors.

In the first block **1110**, the database server **370** obtains the relevant sensor data.

In block **1120**, the database server **370** analyzes the sensor data relative to one or more triggers to determine whether any of the triggers have been satisfied such that a trigger message is to be sent to the patient **230** (e.g., the message **225** illustrated in FIG. **2**), the support person **330**, and/or the caregiver **332**. For example, a trigger may have been entered into the website **217** indicating that if the patient's physical activity drops below a specified level, a trigger message is to be sent to the patient **230**, the support person **330**, and/or the caregiver **332** reporting unusual inactivity. By way of another example, increased peripheral edema measurements might trigger a predetermined prescribed treatment plan that could include increasing a dosage of a diuretic or other medication. By way of yet another example, a combination of sensor measurements (e.g., measurements indicating increased edema and reduced activity) may trigger additional stress testing, automated patient symptom questions, a nurse to call or messages to setup an appointment with a healthcare provider. In block **1120**, the database server **370** may try to identify a trend indicative of a problem.

In decision block **1130**, the database server **370** determines whether one or more triggers are satisfied indicating a problem. The decision in decision block **1130** is "YES" when the database server **370** determines one or more triggers are satisfied. On the other hand, the decision in decision block **1130** is "NO" when the database server **370** determines none of the triggers are satisfied.

When the decision in decision block **1130** is "NO," in optional block **1140**, the database server **370** may send a notification indicating no problem has been detected to the device **10**, the patient desktop computer **335**, the patient cellular telephone **350**, the patient portable computer **355**, and the like to be viewed by patient **230**. The notification may be viewable on the website **217** (see FIG. **2**). Optionally, the database server **370** may send a notification indicating no problem has been detected to the computing device **310** to be viewed by the support person **330** and/or to the computing device **315** to be viewed by the caregiver **332**. Any such notifications may be viewable on the website **217** (see FIG. **2**). Then, the method **800** terminates.

When the decision in decision block **1130** is "YES," in block **1150**, the database server **370** may send a trigger message indicating a problem has been detected to the device **10**, the patient desktop computer **335**, the patient cellular telephone **350**, the patient portable computer **355**, and the like to be viewed by patient **230**. The trigger message may be viewable on the website **217** (see FIG. **2**).

Optionally, the database server **370** may send a trigger message indicating a problem has been detected to the computing device **310** to be viewed by the support person **330** and/or to the computing device **315** to be viewed by the caregiver **332**. Any such trigger messages may be viewable on the website **217** (see FIG. **2**). Instructions may be associated with the trigger and included in the message sent to the patient **230**, the support person **330**, and/or the caregiver **332**. For example, the trigger message may instruct the patient **230** to engage in a particular physical activity (e.g., a stress test) for the purposes of collecting patient data during the physical activity. The collection of such data may be coordinated using the website **217**. As the patient **230** engages in the particular physical activity, the device **10** collects data (using the accelerometer **405**, the heart rate sensor **415**, the oximeter **420**, the sensor **450**, the sensor **455**, and/or the sensor **460**) and transfers the data collected to the control system **220**. Then, the method **1100** terminates.

Feedback may be used to improve the system **200** using retrospective analysis. A website or telephone interaction, for example, may be used to provide a convenient means of feeding information back to the control system **220** regarding decompensation events, if any occur. The patient history can be reviewed to improve of the performance of the control system **220**. In cases where the caregiver **332** (or other healthcare professional) is available by telephone, the system **200** may be used to trigger prospective interaction with the patient **230** that the caregiver **332** may enter into the patient record. In this manner, the system **200** may acquire additional information that may be used to improve the

ability of the system to recognize problems. Further, the system **200** may use such information to provide an earlier indication of a problem that may be reversible by simple measures, such as improved treatment plan compliance, additional medication, reduced salt intake, and the like, which may be implemented before the patient **230** requires emergency healthcare system intervention.

Device **10**

As described above, FIG. **4** illustrates the circuit **400** that may be used to construct the device **10**. Referring to FIGS. **13-18** other components that may be used to construct the device **10** will be described.

Turning to FIG. **17**, in the embodiment illustrated, the circuit **400** is mounted on a substrate **1505** (e.g., a printed circuit board) housed inside a two-part electronics enclosure **1335**. A removable battery **1620** may provide power to the circuit **400**. An insulator **1805** may be positioned adjacent the circuit **400** to allow the battery **1620** to be changed without contacting the circuit **400**. The electronics enclosure **1335** includes a body portion **1540** and a transparent cover **1810**. The body portion **1540** may include a compliant, elastomeric portion **1535** that is positioned against the patient's limb **11** when the device **10** is worn. The body portion **1540** is substantially fluid tight to prevent fluid ingress. The electronics enclosure **1335** may be positioned inside the frame member **1337** having a hook **1330** spaced part from the guide portion **1315**.

Turning to FIG. **13**, in the embodiment illustrated, the first end portion **1312** of the strap **1310** is connected to the frame member **1337** surrounding the electronics enclosure **1335** by the tensioning member **1320** and the second end portion **1314** of the strap **1310** is connected to the guide portion **1315** of the frame member **1337**.

The first end portion **1312** of the strap **1310** extends around the tensioning member **1320** and is affixed to itself. For example, the first end portion **1312** of the strap **1310** may be looped around the tensioning member **1320**, folded back on itself, and affixed in place by an adhesive material **1345**. A guide **1340** spaced apart from the tensioning member **1320** may also be adhered to the first end portion **1312** of the strap **1310** by the adhesive material **1345**. The guide **1340** may be configured to limit lateral movement of the first end portion **1312** of the strap **1310** to help maintain the optical gradient **1545** adjacent the sensors **450**, **455**, and **460**, even when the device **10** is positioned on a portion of the patient's limb **11** (see FIG. **1**) at a location of extreme taper. By way of a non-limiting example, the adhesive material **1345** may include a double stick adhesive, such as 3M 5952 (3M, St Paul, Minn.) or similar adhesive material.

The second end portion **1314** of the strap **1310** is removably or repositionally affixed to itself by a different adhesive tape **1325**, such as 3M 9425 or similar adhesive material. The second end portion **1314** of the strap **1310** is looped around the guide portion **1315** of the frame member **1337**, folded back on itself, and removably fixed in place by the adhesive tape **1325**. The second end portion **1314** of the strap **1310** may be repositioned to adjust the length of the strap **1310** to allow for a large range of circumference changes and for use with a variety of small and large limbs.

The strap **1310** is flexible, substantially inelastic, and resists stretching when worn by the patient **230** (see FIG. **1**). By way of a non-limiting example, the strap **1310** may be constructed from an inelastic material, such as Tyvek (Dupont, Wilmington, Del.) or other similar material.

Referring to FIG. **15**, as mentioned above, the sensor portion **1515** of the electronics enclosure **1335** extends under the first end portion **1312** of the strap **1310** and the optical gradient **1545** is positioned on the first end portion **1312** of the strap **1310** to face the sensor portion **1515** of the electronics enclosure **1335**. The emitter "E**1**" and detector "D**1**" of the sensor **450**, the emitter "E**2**" and detector "D**2**" of the sensor **455**, and the emitter "E**3**" and detector "D**3**" of the sensor **460** are positioned on the sensor portion **1515** of the electronics enclosure **1335** with the emitters and detectors facing toward the optical gradient **1545** on the first end portion **1312** of the strap **1310**.

The tensioning member **1320** may be coupled to the hook **1330** of the frame member **1337**. Tension in the tensioning member **1320** pulls the first end portion **1312** toward the electronics enclosure **1335** to thereby impart tension in the strap **1310**, which may hold the strap **1310** snuggly against the limb **11**. Further, the tensioning member **1320** may help maintain the position of the gradient surface **1545** adjacent to the sensor portion **1515** of the electronics enclosure **1335**. This tensioning member **1320** allows the first and second end portions **1312** and **1314** of the strap **1310** to skew relative to one another (to define the angle "θ" illustrated in FIGS. **10**A and **10**C) and allows the strap to follow the surface of the limb **11**.

At least a portion of the sensor portion **1515** of the electronics enclosure **1335** may be transparent to the light emitted by the emitters "E**1**," "E**2**," and "E**3**" (e.g., red and infrared radiation having a wavelength between about 600 nm to about 1000 nm). In the embodiment illustrated, the transparent cover **1810** that allows light emitted by the emitters "E**1**," "E**2**," and "E**3**" to pass therethrough to illuminate the optical gradient **1545**. A portion of the light emitted by the emitters "E**1**," "E**2**," and "E**3**" is reflected back toward the detectors "D**1**," "D**2**," and "D**3**" positioned inside the sensor portion **1515** of the electronics enclosure **1335**. The reflected light passes through the transparent cover **1810** and into the sensor portion **1515** of the electronics enclosure **1335** where it is detected by the detectors "D**1**," "D**2**," and "D**3**."

The amount of light reflected back toward the sensor portion **1515** is proportional to the position of the detectors "D**1**" and "D**3**" relative to the gradient portions "G**1**" and "G**2**," respectively. The light sensed by the detectors "D**1**" and "D**3**" may be correlated to the position of the device **10** on the limb **11**.

Optionally, the device **10** may include a display (not shown), such as a liquid crystal display, configured to display messages sent to the device.

In an alternate embodiment, referring to FIG. **4**, the radio **430** and the antenna **425** are omitted from the circuit **400**. Instead, referring to FIG. **18**, in a device **1700**, the circuit **400** is configured to communicate via a wired connection **1710** with an external computing device (e.g., the patient desktop computer **335**, the patient cellular telephone **350**, the patient portable computer **355**, and the like). The wired connection **1710** includes a cable **1715** connected at one end to the circuit **400** and at the opposite end to a connector **1720** (e.g., a universal serial bus connector). The connector **1720** may be configured to receive power from the external computing device. In such embodiments, the circuit **400** may be powered by the wired connection **1710**, instead of the battery **1620**.

In another alternate embodiment, the device **10** may be configured to store measurements (and other data), and display information directly to the patient **230**. In such an embodiment, the device **10** may analyze the stored data, or alternatively, be connected to an external communications device configured to transfer the data for analysis by an external computing device (e.g., the database server **370**).

When the analysis is completed, the results may be transferred to the device for display thereby.

The width of the strap **1310** may be selected such that the strap intimately and contiguously follows the surface of the limb **11** and at the same time properly places the sensors **450**, **455**, and **460** relative to the optical gradient **1545**. By way of a non-limiting example, the strap **1310** may be about 25 mm wide. Further, the sensor **450** may be spaced about 20 mm from the sensor **460**.

Declines in patient activity level have also been found to correlate to impending decompensation. Therefore, the accelerometer **405** may be used to measuring patient activity and transmit such information to the control system **220** for analysis thereby to detect trends in general patient activity. The control system **220** may also detect falls and recognize leg orientation to better understand variations in patient activity. The control system **220** may be configured to recognize a substantial variation in patient activity alone as a predictor of a medical problem. In response to detecting a substantial variation in patient activity, the control system **220** may send a message to the patient **230** (via the patient desktop computer **335**, the patient cellular telephone **350**, the patient portable computer **355**, and the like), the support network **210** (e.g., via the computing device **310**), and/or the healthcare system **205** (e.g., via the computing device **315**). Further, the circuit **400** may be modified to include sensors for detecting other physiological parameters such as impedance, respiration, electrocardiogram ("ECG"), and or pulse velocity non-invasive blood pressure ("NIBP"). Physiological parameters sensed by the circuit **400** may be stored, analyzed, and displayed locally on the device **10**, or communicated to an external computing device.

The control system **220** may send instructions to the device **10**. For example, the control system **220** may instruct the device **10** to collect measurements from particular sensors, change the schedule (e.g., intervals) when measurements are collected, display status information, modify (e.g., update) local software programs, and the like.

The control system **220** may route messages to the patient **230**, the support person **330**, and/or the caregiver **332** in a scheduled or event driven manner. Not all significant heart failure symptoms are objective, physiological measurements. Scheduled messages sent to the patient (e.g., sent via the patient cellular telephone **350**) including questions regarding breathlessness, as an example, might be used to gather information useful for generating a trend baseline of the patient's condition. Event driven messages might request that the patient **230**, as an example, perform particular actions (e.g., perform a walking stress test) to characterize the significance of changes observed in the patient's physiological conditions. The control system **220** may analyze data as it is received (in view of the patient record), route messages, and initiate actions as required.

Thus, the system **200** implements a feedback or control loop is created in which the control system **220** may immediately recognize a swelling trend in the patient's limb **11**. A heart failure patient can substantially affect the progression of the disease by compliance with a treatment plan, which may include medication, diet, and exercise. The system **200** may reinforce compliance by providing a means for patients to connect with each other by messaging, voice, and chat room options.

While the sensors **450**, **455**, and **460** have been described as being light sensors, those of ordinary skill in the art appreciate that embodiments may be constructed using other types of sensors, such as linear variable resistors, rotary variable resistors, pressure sensors, strain sensors, magnetoresistive circuits, conductive fabric, conductive elastomers, and the like. Additionally, embodiments may be constructed using sensors that measure capacitance, inductance, magnetorestrictive, Hall Effect, optical pattern encoding, optical path measurement, light loss bending constructions, piezo effect, eddy current, ultrasound, and/or radar.

The device **10** has been described as including sensors **450**, **455**, and **460** configured for use with an optical gradient **1545**. However, other methods may be used to determine whether the distance around the limb **11** has changed. For example, sensors configured to sense strain or pressure may be used.

Further, the system **200** may be configured to receive circumference measurements from devices other than the device **10** and use those measurements to evaluate the circumference of the patient's limb.

Computing Device

FIG. **19** is a diagram of hardware and an operating environment in conjunction with which implementations of the database server **370**, the patient desktop computer **335**, the patient cellular telephone **350**, the patient portable computer **355**, the support computing device **310**, the caregiver computing device **315**, and the web server **318** may be practiced. The description of FIG. **19** is intended to provide a brief, general description of suitable computer hardware and a suitable computing environment in which implementations may be practiced. Although not required, implementations are described in the general context of computer-executable instructions, such as program modules, being executed by a computer, such as a personal computer. Generally, program modules include routines, programs, objects, components, data structures, etc., that perform particular tasks or implement particular abstract data types.

Moreover, those skilled in the art will appreciate that implementations may be practiced with other computer system configurations, including hand-held devices, multiprocessor systems, microprocessor-based or programmable consumer electronics, network PCs, minicomputers, mainframe computers, and the like. Implementations may also be practiced in distributed computing environments where tasks are performed by remote processing devices that are linked through a communications network. In a distributed computing environment, program modules may be located in both local and remote memory storage devices.

The exemplary hardware and operating environment of FIG. **19** includes a general-purpose computing device in the form of a computing device **12**. The database server **370**, the patient desktop computer **335**, the patient cellular telephone **350**, the patient portable computer **355**, the support computing device **310**, the caregiver computing device **315**, the web server **318** may each be implemented using one or more computing devices like the computing device **12**.

The computing device **12** includes a system memory **22**, the processing unit **21**, and a system bus **23** that operatively couples various system components, including the system memory **22**, to the processing unit **21**. There may be only one or there may be more than one processing unit **21**, such that the processor of computing device **12** includes a single central-processing unit ("CPU"), or a plurality of processing units, commonly referred to as a parallel processing environment. When multiple processing units are used, the processing units may be heterogeneous. By way of a non-limiting example, such a heterogeneous processing environment may include a conventional CPU, a conventional graphics processing unit ("GPU"), a floating-point unit ("FPU"), combinations thereof, and the like.

The computing device **12** may be a conventional computer, a distributed computer, or any other type of computer.

The system bus **23** may be any of several types of bus structures including a memory bus or memory controller, a peripheral bus, and a local bus using any of a variety of bus architectures. The memory **410** (illustrated FIG. **4**) may be substantially similar to the system memory **22**. The system memory **22** may also be referred to as simply the memory, and includes read only memory (ROM) **24** and random access memory (RAM) **25**. A basic input/output system (BIOS) **26**, containing the basic routines that help to transfer information between elements within the computing device **12**, such as during start-up, is stored in ROM **24**. The computing device **12** further includes a hard disk drive **27** for reading from and writing to a hard disk, not shown, a magnetic disk drive **28** for reading from or writing to a removable magnetic disk **29**, and an optical disk drive **30** for reading from or writing to a removable optical disk **31** such as a CD ROM, DVD, or other optical media.

The hard disk drive **27**, magnetic disk drive **28**, and optical disk drive **30** are connected to the system bus **23** by a hard disk drive interface **32**, a magnetic disk drive interface **33**, and an optical disk drive interface **34**, respectively. The drives and their associated computer-readable media provide nonvolatile storage of computer-readable instructions, data structures, program modules, and other data for the computing device **12**. It should be appreciated by those skilled in the art that any type of computer-readable media which can store data that is accessible by a computer, such as magnetic cassettes, flash memory cards, solid state memory devices ("SSD"), USB drives, digital video disks, Bernoulli cartridges, random access memories (RAMs), read only memories (ROMs), and the like, may be used in the exemplary operating environment. As is apparent to those of ordinary skill in the art, the hard disk drive **27** and other forms of computer-readable media (e.g., the removable magnetic disk **29**, the removable optical disk **31**, flash memory cards, SSD, USB drives, and the like) accessible by the processing unit **21** may be considered components of the system memory **22**.

A number of program modules may be stored on the hard disk drive **27**, magnetic disk **29**, optical disk **31**, ROM **24**, or RAM **25**, including an operating system **35**, one or more application programs **36**, other program modules **37**, and program data **38**. A user may enter commands and information into the computing device **12** through input devices such as a keyboard **40** and pointing device **42**. Other input devices (not shown) may include a microphone, joystick, game pad, satellite dish, scanner, touch sensitive devices (e.g., a stylus or touch pad), video camera, depth camera, or the like. These and other input devices are often connected to the processing unit **21** through a serial port interface **46** that is coupled to the system bus **23**, but may be connected by other interfaces, such as a parallel port, game port, a universal serial bus (USB), or a wireless interface (e.g., a Bluetooth interface). A monitor **47** or other type of display device is also connected to the system bus **23** via an interface, such as a video adapter **48**. In addition to the monitor, computers typically include other peripheral output devices (not shown), such as speakers, printers, and haptic devices that provide tactile and/or other types physical feedback (e.g., a force feed back game controller).

The input devices described above are operable to receive user input and selections. Together the input and display devices may be described as providing a user interface. The input devices may be used to receive information from the patient **230**, the support person **330**, the caregiver **332**, and the like. The user interface may be used to display messages (e.g., notifications and alters) to the patient **230**, the support person **330**, the caregiver **332**, and the like.

The computing device **12** may operate in a networked environment using logical connections to one or more remote computers, such as remote computer **49**. These logical connections are achieved by a communication device coupled to or a part of the computing device **12** (as the local computer). Implementations are not limited to a particular type of communications device. The remote computer **49** may be another computer, a server, a router, a network PC, a client, a memory storage device, a peer device or other common network node, and typically includes many or all of the elements described above relative to the computing device **12**. The remote computer **49** may be connected to a memory storage device **50**. The logical connections depicted in FIG. **10** include a local-area network (LAN) **51** and a wide-area network (WAN) **52**. Such networking environments are commonplace in offices, enterprise-wide computer networks, intranets and the Internet.

Those of ordinary skill in the art will appreciate that a LAN may be connected to a WAN via a modem using a carrier signal over a telephone network, cable network, cellular network, or power lines. Such a modem may be connected to the computing device **12** by a network interface (e.g., a serial or other type of port). Further, many laptop computers may connect to a network via a cellular data modem.

When used in a LAN-networking environment, the computing device **12** is connected to the local area network **51** through a network interface or adapter **53**, which is one type of communications device. When used in a WAN-networking environment, the computing device **12** typically includes a modem **54**, a type of communications device, or any other type of communications device for establishing communications over the wide area network **52**, such as the Internet. The modem **54**, which may be internal or external, is connected to the system bus **23** via the serial port interface **46**. In a networked environment, program modules depicted relative to the personal computing device **12**, or portions thereof, may be stored in the remote computer **49** and/or the remote memory storage device **50**. It is appreciated that the network connections shown are exemplary and other means of and communications devices for establishing a communications link between the computers may be used.

The computing device **12** and related components have been presented herein by way of particular example and also by abstraction in order to facilitate a high-level view of the concepts disclosed. The actual technical design and implementation may vary based on particular implementation while maintaining the overall nature of the concepts disclosed.

The memory of the database server **370** stores computer executable instructions that when executed by one or more processors cause the one or more processors to perform all or portions of the methods **700**, **750**, **800**, and/or **1100**.

The memory **410** of the device **10** stores processor executable instructions that when executed by the processor **435** cause the processor to perform all or portions of the methods **500**, **600**, **650**, **750**, **800**, and/or **1100**.

Any of the instructions described above, including the instructions of stored by the memory of the database server **370** and in the memory **410** of the device **10**, may be stored on one or more non-transitory computer-readable media.

The foregoing described embodiments depict different components contained within, or connected with, different other components. It is to be understood that such depicted

architectures are merely exemplary, and that in fact many other architectures can be implemented which achieve the same functionality. In a conceptual sense, any arrangement of components to achieve the same functionality is effectively "associated" such that the desired functionality is achieved. Hence, any two components herein combined to achieve a particular functionality can be seen as "associated with" each other such that the desired functionality is achieved, irrespective of architectures or intermedial components. Likewise, any two components so associated can also be viewed as being "operably connected," or "operably coupled," to each other to achieve the desired functionality.

While particular embodiments of the present invention have been shown and described, it will be obvious to those skilled in the art that, based upon the teachings herein, changes and modifications may be made without departing from this invention and its broader aspects and, therefore, the appended claims are to encompass within their scope all such changes and modifications as are within the true spirit and scope of this invention. Furthermore, it is to be understood that the invention is solely defined by the appended claims. It will be understood by those within the art that, in general, terms used herein, and especially in the appended claims (e.g., bodies of the appended claims) are generally intended as "open" terms (e.g., the term "including" should be interpreted as "including but not limited to," the term "having" should be interpreted as "having at least," the term "includes" should be interpreted as "includes but is not limited to," etc.). It will be further understood by those within the art that if a specific number of an introduced claim recitation is intended, such an intent will be explicitly recited in the claim, and in the absence of such recitation no such intent is present. For example, as an aid to understanding, the following appended claims may contain usage of the introductory phrases "at least one" and "one or more" to introduce claim recitations. However, the use of such phrases should not be construed to imply that the introduction of a claim recitation by the indefinite articles "a" or "an" limits any particular claim containing such introduced claim recitation to inventions containing only one such recitation, even when the same claim includes the introductory phrases "one or more" or "at least one" and indefinite articles such as "a" or "an" (e.g., "a" and/or "an" should typically be interpreted to mean "at least one" or "one or more"); the same holds true for the use of definite articles used to introduce claim recitations. In addition, even if a specific number of an introduced claim recitation is explicitly recited, those skilled in the art will recognize that such recitation should typically be interpreted to mean at least the recited number (e.g., the bare recitation of "two recitations," without other modifiers, typically means at least two recitations, or two or more recitations).

Accordingly, the invention is not limited except as by the appended claims.

What is claimed is:

1. A system, comprising:

one or more non-transitory storage media configured to provide stored computer-readable instructions, the one or more non-transitory storage media coupled to one or more processors, the one or more processors configured to execute the computer-readable instructions to cause the one or more processors to perform acts comprising:

receiving, over a network from one or more sensors of a patient monitoring device, measurements of patient physical activity associated with a patient;

receiving reference information comprising trigger values corresponding to the measurements of patient physical activity and instructions associated with the trigger values;

comparing the measurements of patient physical activity with the corresponding trigger values;

determining, from the comparison, whether one or more of the measurements of patient physical activity indicate that the patient physical activity is declining based at least on the compared measurements exceeding the corresponding trigger values;

in response to determining that the patient physical activity is declining, predicting a future medical problem based on the one or more measurements that exceed the corresponding trigger values, retrieving the instructions corresponding with the corresponding trigger values, and instructing, over a network, the patient monitoring device to collect measurements from particular sensors of the one or more sensors, the instructions directed to at least reducing a likelihood of the future medical problem from occurring.

2. The system of claim **1**, wherein the instructions associated with the trigger values comprise a predefined treatment plan corresponding to one or more medical conditions of the patient.

3. The system of claim **2**, wherein the acts further comprise:

calculate a modified dosage of at least one medication of the patient based at least on the predefined treatment plan.

4. The system of claim **1**, wherein the acts further comprise:

receiving heart rate measurements of the patient,

wherein the message instructs the patient to follow a treatment plan that includes exercise based at least on the heart rate measurements.

5. The system of claim **1**, wherein the acts further comprise:

receiving heart rate measurements of the patient, wherein the message instructs the patient to perform a predetermined physical activity based at least on the heart rate measurements;

monitoring the heart rate measurements of the patient while the patient performs the predetermined physical activity

in response to determining that the heart rate measurements exceed a predetermined threshold, generating a modified physical activity based at least on the heart rate measurements.

6. The system of claim **1**, wherein the acts further comprise:

receiving heart rate measurements of the patient, wherein the message instructs the patient to perform a predetermined physical activity based at least on the heart rate measurements; and

receiving blood oxygen measurements of the patient while the patient performs the predetermined physical activity.

7. The system of claim **1**, wherein the acts further comprise:

identifying a trend indicative of an issue associated with the decline in the patient physical activity.

8. A computer-implemented method comprising:

receiving, over a network from one or more sensors of a patient monitoring device, measurements of patient physical activity associated with a patient,

receiving reference information comprising trigger values corresponding to the measurements of patient physical activity and instructions associated with the trigger values;

comparing the measurements of patient physical activity with the corresponding trigger values;

determining, from the comparison, whether one or more of the measurements of patient physical activity indicate that the patient physical activity is declining based at least on the compared measurements exceeding the corresponding trigger values;

in response to determining that the patient physical activity is declining, predicting a future medical problem based on the one or more measurements that exceed the corresponding trigger values, retrieving the instructions corresponding with the corresponding trigger values, and instructing, over a network, the patient monitoring device to collect measurements from particular sensors of the one or more sensors.

9. The computer-implemented method of claim **8**, wherein the instructions associated with the trigger values comprise a predefined treatment plan corresponding to one or more medical conditions of the patient.

10. The computer-implemented method of claim **9**, further comprising:

calculating a modified dosage of at least one medication of the patient based at least on the predefined treatment plan.

11. The computer-implemented method of claim **8**, further comprising:

receiving heart rate measurements of the patient,

wherein the message instructs the patient to perform a predetermined physical activity based at least on the heart rate measurements.

12. The computer-implemented method of claim **11**, further comprising:

monitoring the heart rate measurements of the patient while the patient performs the predetermined physical activity; and

in response to determining that the heart rate measurements exceed a predetermined threshold, generating a modified physical activity based at least on the heart rate measurements.

13. The computer-implemented method of claim **11**, further comprising:

receiving blood oxygen measurements of the patient while the patient performs the predetermined physical activity.

14. The computer-implemented method of claim **8**, further comprising:

identifying a trend indicative of an issue associated with the decline in the patient physical activity.

15. One or more non-transitory computer-readable media storing computer-executable instructions that upon execution cause one or more processors to perform acts comprising:

receiving, over a network from one or more sensors of a patient monitoring device, measurements of patient physical activity associated with a patient;

receiving reference information comprising trigger values corresponding to the measurements of patient physical activity and instructions associated with the trigger values;

comparing the measurements of patient physical activity with the corresponding trigger values;

determining, from the comparison, whether one or more of the measurements of patient physical activity indicate that the patient physical activity is declining based at least on the compared measurements exceeding the corresponding trigger values;

in response to determining that the patient physical activity is declining, predicting a future medical problem based on the one or more measurements that exceed the corresponding trigger values, and instructing, over a network, the patient monitoring device to collect measurements from particular sensors of the one or more sensors.

16. The one or more non-transitory computer-readable media of claim **15**, wherein the instructions associated with the trigger values comprise a predefined treatment plan corresponding to one or more medical conditions of the patient.

17. The one or more non-transitory computer-readable media of claim **16**, wherein the acts further comprise:

calculating a modified dosage of at least one medication of the patient based at least on the predefined treatment plan.

18. The one or more non-transitory computer-readable media of claim **15**, wherein the acts further comprise:

receiving heart rate measurements and blood oxygen measurements of the patient,

wherein the message instructs the patient to perform a predetermined physical activity based at least on the heart rate measurements and the blood oxygen measurements.

19. The one or more non-transitory computer-readable media of claim **18**, wherein the acts further comprise:

monitoring the heart rate measurements of the patient while the patient performs the predetermined physical activity; and

in response to determining that the heart rate measurements exceed a predetermined threshold, generating a modified physical activity based at least on the heart rate measurements.

20. The one or more non-transitory computer-readable media of claim **15**, wherein the acts further comprise:

triggering one or more additional stress testing in response to determining that the patient physical activity is declining.

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