



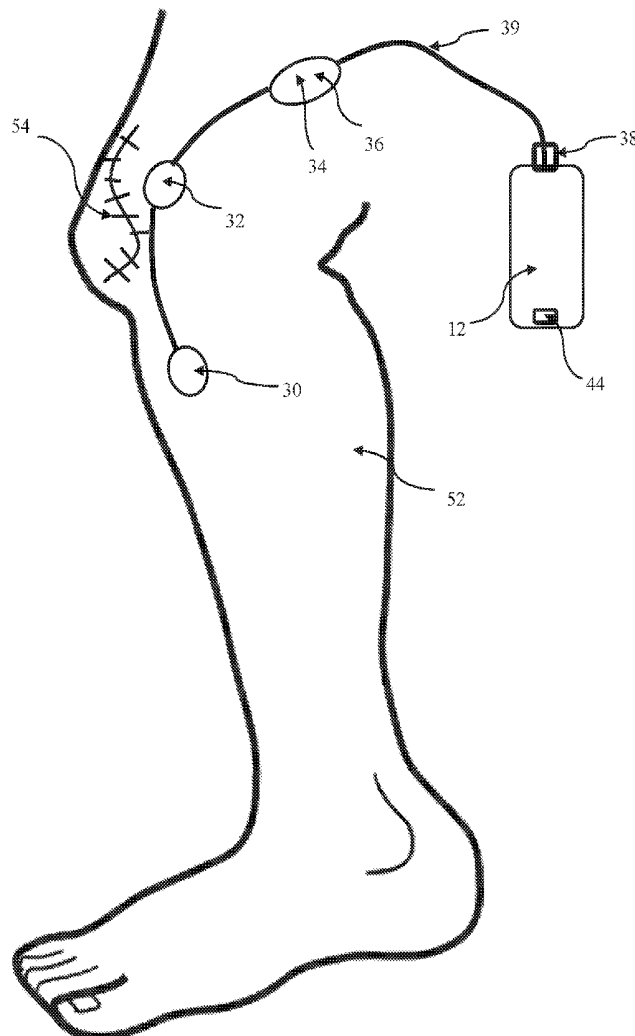
US 20170265800A1

(19) **United States**(12) **Patent Application Publication**
Auchinleck et al.(10) **Pub. No.: US 2017/0265800 A1**(43) **Pub. Date: Sep. 21, 2017**(54) **APPARATUS AND METHOD FOR
MONITORING REHABILITATION FROM
JOINT SURGERY**(71) Applicant: **Claris Healthcare Inc.**, Vancouver
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Stefan Fletcher, Victoria (BC)(21) Appl. No.: **15/070,341**(22) Filed: **Mar. 15, 2016****Publication Classification**(51) **Int. Cl.**
A61B 5/00 (2006.01)
A61B 5/01 (2006.01)
A61B 5/11 (2006.01)
A61B 5/107 (2006.01)(52) **U.S. Cl.**CPC **A61B 5/4528** (2013.01); **A61B 5/1071**
(2013.01); **A61B 5/01** (2013.01); **A61B 5/742**
(2013.01); **A61B 5/7275** (2013.01); **A61B 5/11**
(2013.01); **A61B 5/6828** (2013.01); **A61B**
5/4833 (2013.01); **A61B 2562/0219** (2013.01)

(57)

ABSTRACT

A motion sensor is attached to a patient's limb distal to a joint on which surgery has occurred and another motion sensor is attached to the limb proximate to the joint. In the preferred embodiment, the motion sensors are accelerometers and gyroscopes that are capable of generating data that corresponds to flexion of the joint. Temperature sensors are attached to the patient at the surgical site at the joint and at a site separated from the surgical site so that the temperature difference between the sensors may be monitored. Data from the sensors is used to monitor the patient's post-surgical condition and rehabilitation and to provide feedback to the patient.



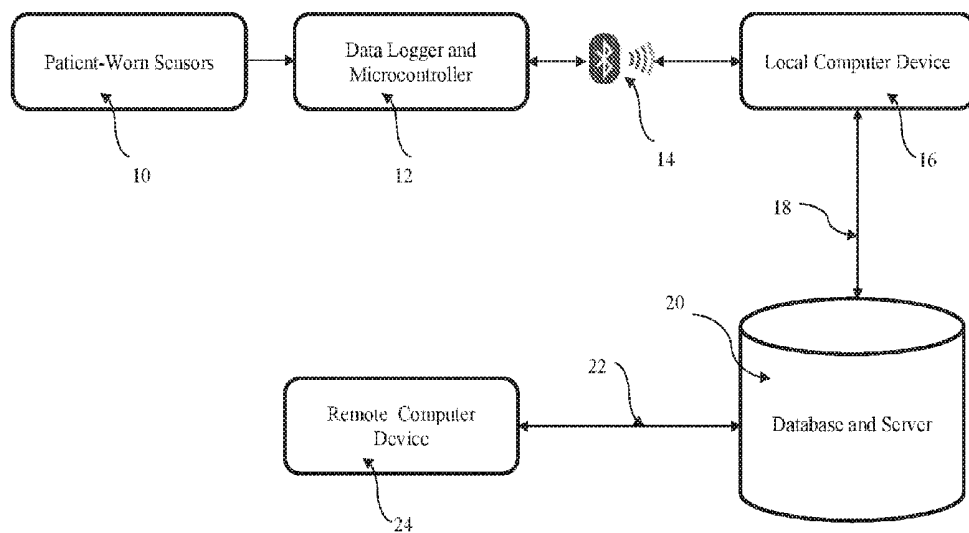


Fig. 1

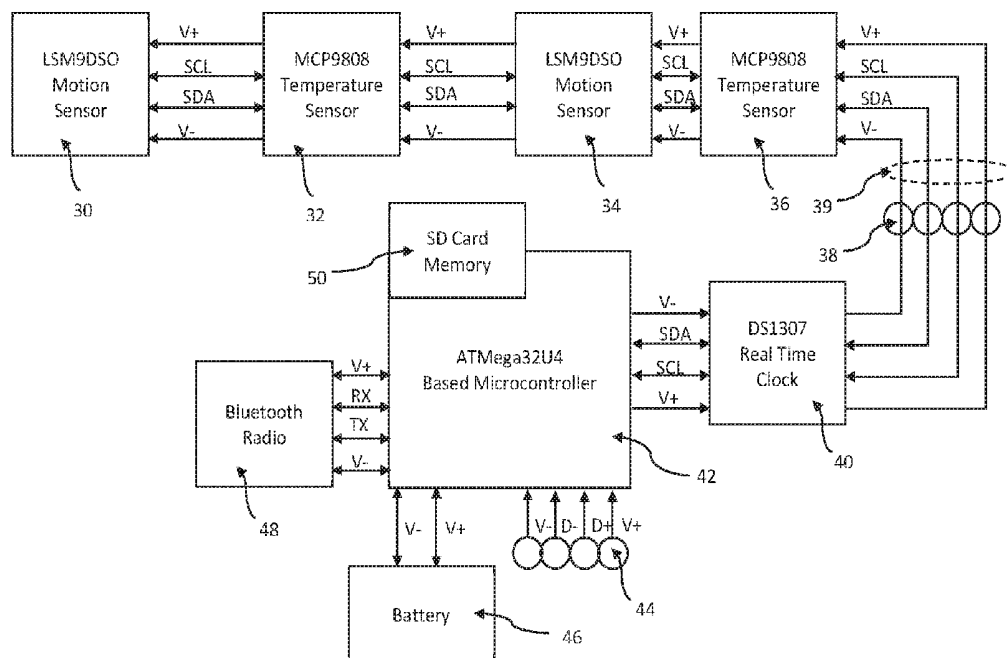


Fig. 2

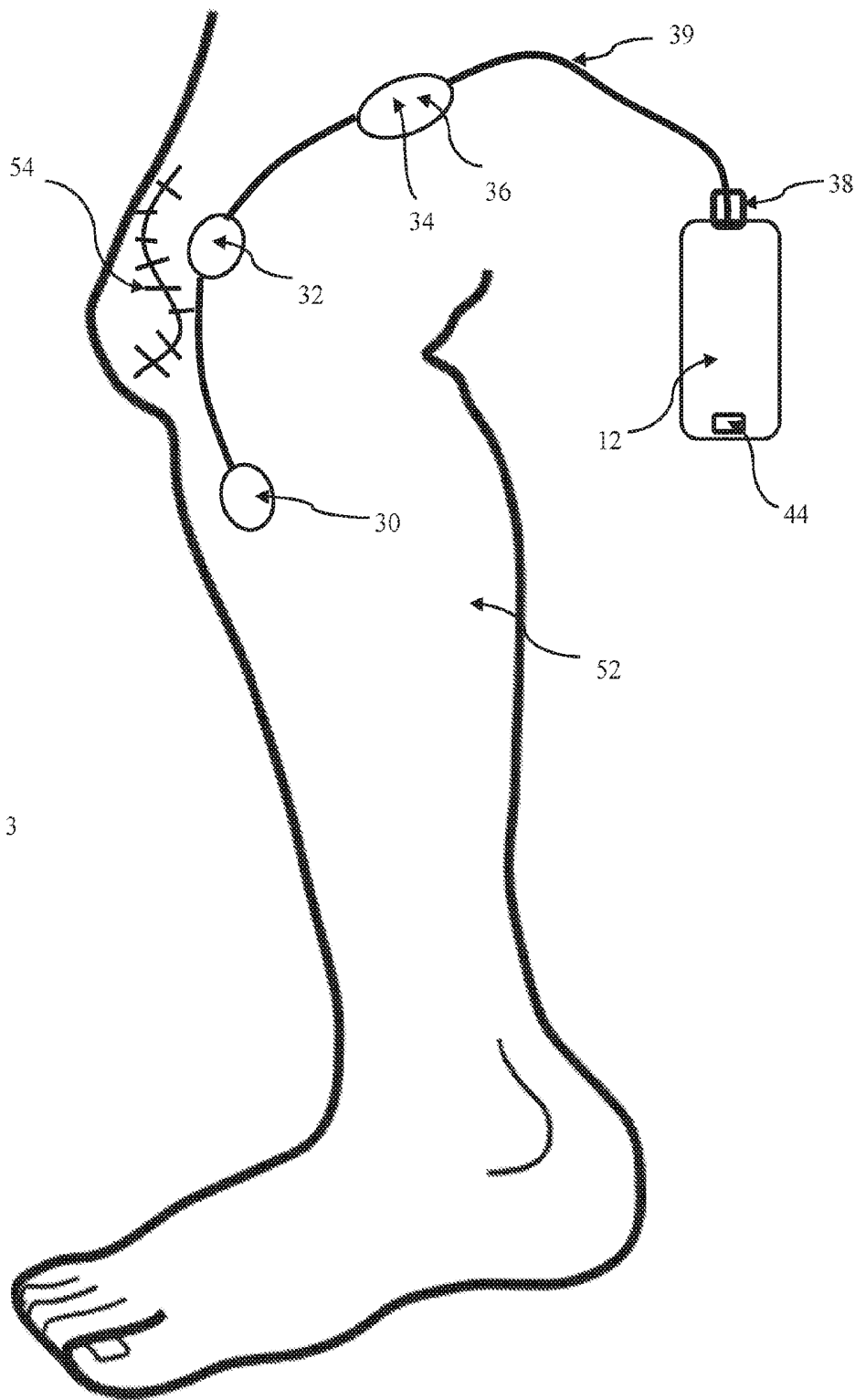


Fig. 3

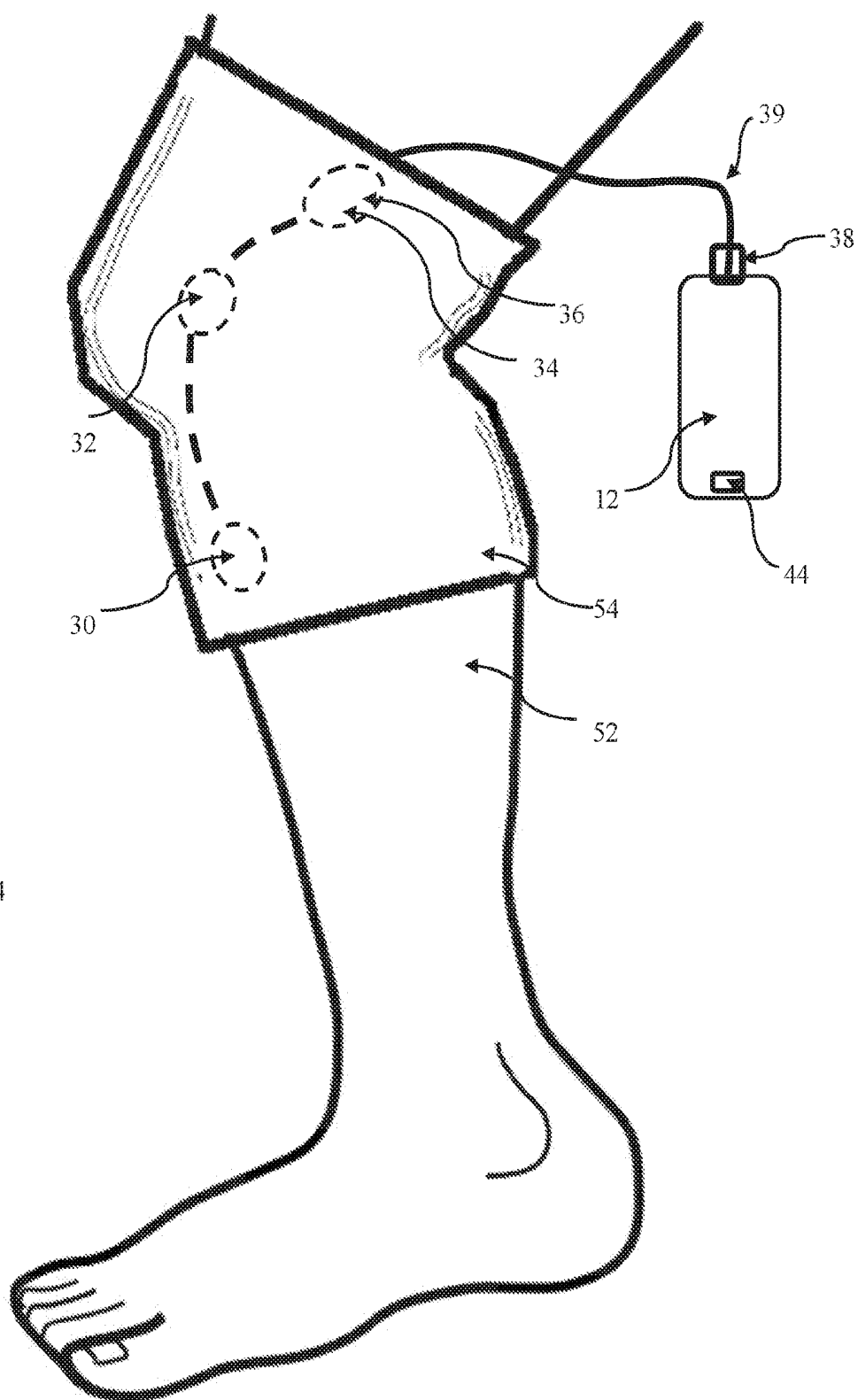


Fig. 4

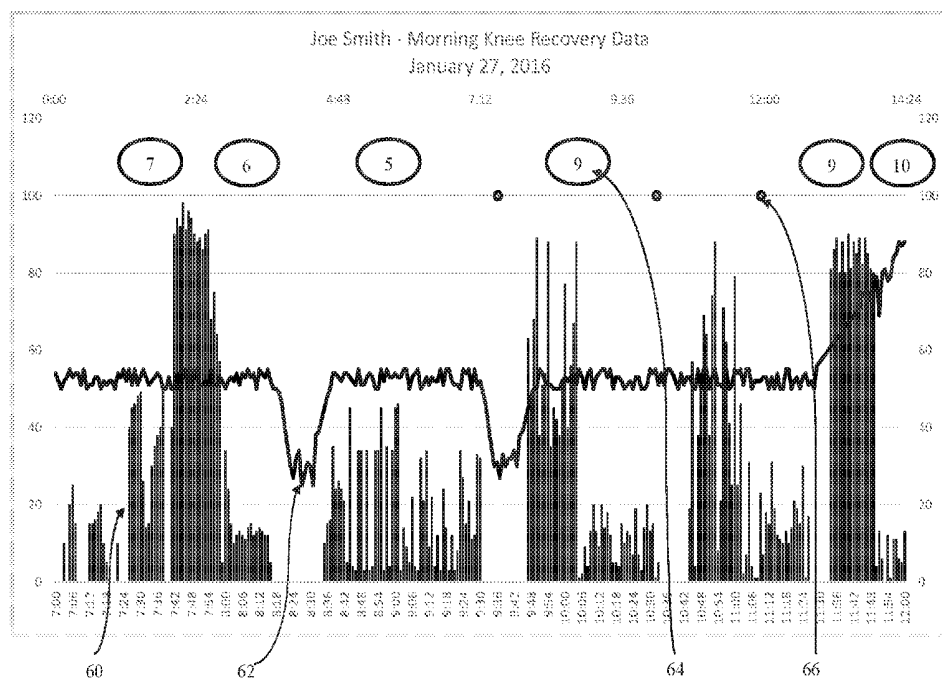


Fig 5.

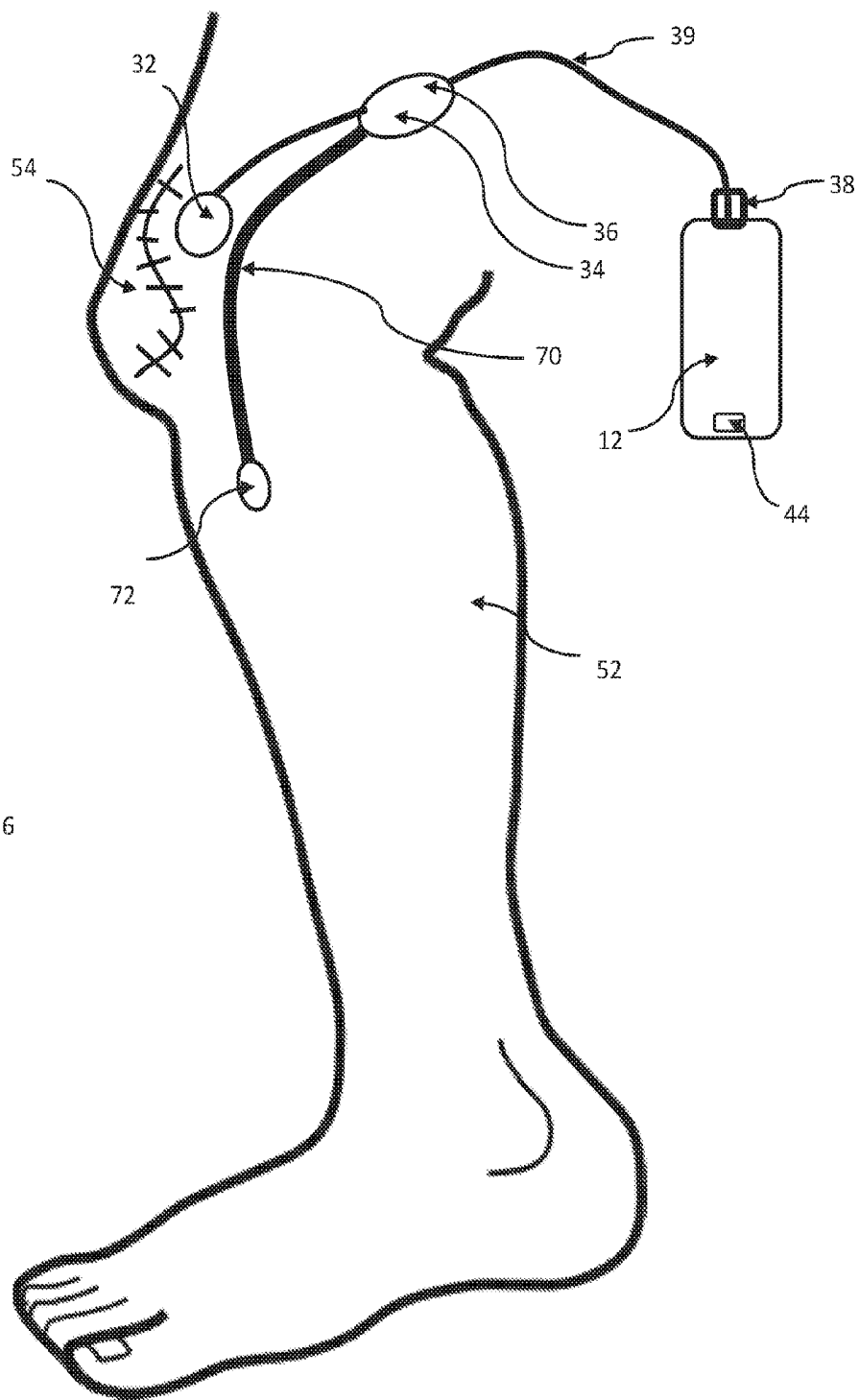


Fig. 6

APPARATUS AND METHOD FOR MONITORING REHABILITATION FROM JOINT SURGERY

FIELD OF THE INVENTION

[0001] The present invention relates to apparatus and methods for monitoring the compliance of a patient to the rehabilitation regimen that is prescribed for preparation for and recovery from joint surgery such as total joint arthroplasty. More specifically, the present invention relates to the use of sensors applied to a post-surgical patient for the purpose of detecting, acquiring and measuring the patient's movement and temperature and for using acquired data for tracking the patient's progress during rehabilitation.

[0002] Joint arthroplasty is a surgical procedure for resurfacing or replacing those parts of knee, hip, elbow, shoulder and other joints that are damaged, typically from arthritis, in older adults. Knee arthroplasty is a very common procedure—more than 700,000 were done in the United States in 2015—and is rapidly increasing as a result of an aging population.

[0003] A key factor in the success of a joint arthroplasty is the compliance of the patient with the required rehabilitation regimen. This regimen may begin prior to surgery—certain exercises and stretches are sometimes prescribed in advance of surgery to improve the chances of success—and is certainly required for some months after the surgery is complete. Rehabilitation may include such activities as flexing the affected joint through a certain range of motion, applying ice or heat to the joint, and monitoring the surgical site for signs of infection or drainage.

[0004] Rehabilitation is usually managed by a physiotherapist or other medical professional who instructs the patient in a clinical setting, then checks with the patient occasionally to monitor their progress. This means that the patient is expected to be self-motivated to follow the required regimen and accurately report to the caregiver their level of compliance. Many find this difficult to do and may not be entirely honest about their level of compliance.

[0005] To encourage better compliance, it would be advantageous to provide a patient with timely feedback and encouragement as to their progress, and to provide quantitative measurements as to their progress, both to the patient and their caregivers.

[0006] Two kinds of measurements can provide information of value. The first is measurement of the number of flexions, degree of flexion and maximum and minimum amount of flexion of the affected joint; the second is measurement of the skin temperature near the surgical site. The number and the degree of flexions including the maximum and minimum flex angles is indicative of the patient's activity level and progress towards re-establishing a full range of motion. The temperature near the wound site can provide an early indication of infection as it has been known since Roman times that wound infection is indicated by the four factors of calor, dolor, rubor and tumor—heat, pain, redness and swelling. Further, icing of the wound site after surgery is indicated for improved recovery, therefore measuring the amount and duration of temperature decrease near the wound site is indicative of the patient's compliance with prescribed icing techniques.

[0007] Using electronic sensors to measure joint flexion has been demonstrated in the laboratory. Several published papers show the use of integrated circuit accelerometers or

capacitive, resistive or inductive flex sensors to detect joint movements and range of motion. Similarly, there are many well-known ways to measure skin temperature using electronic and mechanical thermometers.

[0008] Existing devices for measuring joint motion and temperature require separate sensors connected to a computer for collecting data for interpretation by a caregiver. These systems do not provide a convenient single unit for measuring the required parameters, nor do they provide for storage of the data for later transmission to a caregiver's computer. In addition, a single temperature sensor near the wound site may provide misleading data if the patient moves into a hot or cold environment, as there is no way, with one sensor, to tell if the temperature increase or decrease is a local effect (caused by infection or icing of the joint).

[0009] The prior art also fails to teach the combination of data from motion and temperature sensors into a patient coaching system and caregiver management system. Such a system can be used by a caregiver to set specific goals (such as number of repetitions of joint flexion, target ranges of motion or target temperature and duration during icing) and to provide the patient with feedback and encouragement as to achievement of those goals based on measurements by the sensors.

SUMMARY OF THE INVENTION

[0010] The current invention describes apparatus and method for setting rehabilitation goals for a patient, measuring their movements, storing the movement data for later transfer to a computer, displaying progress indicators and inspirational messages based on progress towards goals, reporting movement and skin temperature data to a caregiver so that they monitor compliance and be aware of potential infection.

[0011] One advantage of the current invention is the use of two temperature sensors to monitor patient skin temperature—one located on the skin near the surgical wound site and another on the skin some distance from the wound site, so that the wound site temperature can be compared to a basal skin temperature, eliminating environmental variations that might effect the temperature measurements.

[0012] In another aspect, the sensor apparatus in accordance with the current invention provides for data storages and wireless communications between the sensor apparatus and a computer or computer network, such that readings made by the sensors can be stored within the sensor apparatus, then transmitted wirelessly to a computer or network whenever a wireless connection is available, therefore eliminating the need for the patient to remain within wireless communications range of a computer, without risking loss of measurement data.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] These and other objects, features and advantages of the present invention will become apparent upon reference to the following detailed description of the exemplary embodiment presented herein and to the drawings wherein:

[0014] FIG. 1 is a block diagram of an apparatus according to the invention.

[0015] FIG. 2 is a schematic representation of the sensor and data logger components of the apparatus shown in FIG. 1.

[0016] FIG. 3 is a schematic illustration of a post-operative patient's leg illustrating how the sensors, data logger and microcontroller may be applied to the patient's leg.

[0017] FIG. 4 is a schematic illustration analogous to FIG. 3 except illustrating an alternative embodiment of an apparatus for locating the sensors on the patient's leg.

[0018] FIG. 5 is a graphical display of how data obtained from patient-worn sensors according the present invention may be displayed on, for example, a computer monitor.

[0019] FIG. 6 is a schematic illustration analogous to FIG. 3, except illustrating an alternative embodiment of an apparatus for measuring the flexion of the patient's leg.

DETAILED DESCRIPTION OF THE INVENTION AND ILLUSTRATED EMBODIMENTS

[0020] FIG. 1 illustrates the major functional components of the preferred embodiment according to the invention. Patient-worn sensors 10 are connected to data logger and microcontroller 12, both of which are described more fully hereinafter, such that the microcontroller can cause data to be read from sensors 10 and stored in memory. At pre-determined intervals, microcontroller 12 tests to see if a connection to local computer 16 can be made through wireless data connection 14, which in the preferred embodiment is a Bluetooth connection, but may be a WiFi or other data connection. If a connection is available, microcontroller 12 retrieves data from sensors 10 from the memory and sends it across wireless data connection 14 to local computer 16. Local computer 16, which in the preferred embodiment is an Android tablet computer, then transfers the data, using Internet connection 18, to database and server 20, which, in the preferred embodiment is a 'cloud service' such as those provided by Heroku and Amazon.

[0021] Also connected to database and server 20 is remote computer 24, via Internet connection 22, which may be any computer capable of running a web browser such as Google Chrome or the like. Thus, it can be seen that through the various devices and connections described, data from sensors 10 can be delivered to database and server 20, from where it can be retrieved by remote computer 24 for viewing and interpretation by a user of remote computer 24.

[0022] Note that Internet connections 18 and 22 permit communications in the opposite direction to that described—remote computer 24 can send information via Internet connection 22 to database and server 20, from whence it can be further sent to local computer 16. In this way it is possible for remote computer 24 to cause computer 16 to display messages, images, videos or other information on local computer 16.

[0023] FIG. 2 more fully illustrates patient worn sensors 10 and data logger and microcontroller 12. In the preferred embodiment, data logger and microcontroller 12 is made up of ATmega32U4 processor board 42, connected to SD card memory unit 50, which in the preferred embodiment is an Adafruit Feather 32u4 Adalogger (Adafruit Industries LLC, NY, N.Y.). Incorporated into processor board 42 is USB connector 44, serial communications connections, I2C bus connections and battery charging circuitry. Battery 46 is a lithium polymer 3.7 volt 12 mAh battery, which in the preferred embodiment is a PKCell LP503562, which is connected to the battery pins of processor board 42.

[0024] Bluetooth radio 48 is embodied with an Adafruit BlueFruit EZ Link module. This module is connected to the

auxiliary power supply connections of processor board 42 and to the serial data transmit (TX) and receive (RX) pins of processor board 42.

[0025] The remaining modules of data logger and microcontroller 12 and patient worn sensors 10 are connected to processor board 42 using the industry standard I2C bus. This communications bus provides electrical power and digital communications to 100 or more modules connected on the same set of four wires. As each device connected to the I2C bus has a unique digital address, the software running on microcontroller 12 can request and receive data from each module as required.

[0026] Real time clock 40 is an I2C module based on the DS1307 real time clock chip. In the preferred embodiment, this is an Adafruit DS1307 Real Time Clock module, which includes a battery backup to ensure that real time clock data is preserved even if battery 46 should become exhausted.

[0027] Also connected to the I2C bus are two MCP9808 temperature sensors (Adafruit MCP9808) and two LSM9DSO motion sensors (Adafruit LSM9DSO). Motion sensor 30 is connected to the distal end of I2C cable 39 so that it may be attached distal to the patient's affected joint as hereinafter described; temperature sensor 32 is connected to the cable 39 some distance proximal to motion sensor 30, such that it may be attached to the patient's skin near the surgical site; and motion sensor 34 and temperature sensor 36, are connected some distance proximal to temperature sensor 32 so that they can be attached to the skin proximal to the patient's affected joint. As detailed below, temperature sensor 32 is attached to the patient near enough to the surgical site that the sensor is capable of measuring increases (or decreases) in temperature at the surgical site, which could be indicative of infection (or icing). Temperature sensor 36 is attached to the patient spaced away from sensor 32 by enough distance that the sensor 36 measures a basal skin temperature that is not effected by an increase or decrease in temperature at the surgical site where the sensor 32 is located.

[0028] Cable 39 connecting real time clock 40 and temperature sensor 36 includes connector 38, which allows the temperatures sensors 32 and 36 and motion sensors 30 and 34 to be disconnected from real time clock 40, thus making the module containing real time clock 40, processor board 42, Bluetooth radio 48, SD card memory 50 and battery 46 separable from the sensor components.

[0029] FIG. 3 shows how patient worn sensors 10 and data logger and microcontroller 12 might be applied to the leg of patient 52 during recovery from knee surgery. Motion sensor 30 is applied to the patient's leg below the knee and may be taped in place, attached to the surgical dressing, or tucked inside an elastic bandage applied to the leg. Similarly, temperature sensor 32 is attached to the leg, but is located as near as practicable to surgical incision 54. In the preferred embodiment, temperature sensor 36 and motion sensor 34 are contained within the same enclosure and are attached to the leg of patient 52 above the knee. All of the sensors are connected with cable 39, which is connected to data logger and microcontroller 12 with connector 38. Microcontroller 12 encloses real time clock 40, processor board 42, SD memory 50, Bluetooth radio 48, battery 46 and USB connector 44. USB connector 44 is accessible such that microcontroller 12 can be plugged into a standard USB cable to recharge battery 46 and to upload programs to processor

board 42. In use, microcontroller 12 may be strapped to the leg of patient 52 with an elastic strap, clipped on a belt, or placed in a pocket.

[0030] FIG. 4 shows an alternative means for locating the sensors on a patient's leg in accordance with the invention, as it might be used in rehabilitation from knee surgery. In this embodiment, sensors 30, 32 34 and 36 are fastened inside elastic sleeve 54, all connected via cable 39. The sensors are pre-positioned at locations inside the sleeve such that when the sleeve is pulled up over the knee, the sensors are located in the desired positions. This has the advantage of simplifying the location and attachment of the sensors to the patient.

[0031] In typical use, a caregiver uses remote computer 24, to create a record for a new patient using a web application hosted by database and server 20. As part of this setup, the caregiver assigns local computer 16 to patient 52, creating a link between the record for the patient and local computer 16. The caregiver then pairs patient worn sensors 10 to local computer 16 so that data from patient worn sensors 10 is transmitted to local computer 16 using Bluetooth connection 14 from where it is further transferred to database and server 20 over Internet connection 18, where it is stored in a database record associated with patient 52.

[0032] As soon as the connection is made, data logger and microcontroller 12 begins to collect data from patient worn sensors 10 and store it locally in SD card memory 50. In the preferred embodiment, data is collected approximately every 1/10 second. From time to time, microcontroller 12 checks to see if there is a connection to local computer 16 available using Bluetooth connection 14. If so, microcontroller 12 transmits any data not previously transmitted to local computer 16. In turn, local computer 16 transmits the data to database and server 20 over Internet connection 18.

[0033] From time to time, the caregiver may choose to review the data collected by patient worn sensors 10. Using a web browser on remote computer 24, the caregiver can retrieve data from database and server 20. The web service running on database and server 20 retrieves the data obtained from patient worn sensors 10 and performs an analysis of the data to extract features from the raw data.

[0034] Many different techniques for extracting knee joint angles from accelerometer and gyroscope data are known in the art, many of which can be implemented with the sensors 30 and 34 herein described. For example, a first approximation of the knee joint angle can be determined using only the three-axis accelerometers of sensors 30 and 34. In this implementation, the acceleration due to gravity is detected by each sensor to provide an X, Y and Z acceleration measurement that varies depending on the orientation of the sensor with respect to the ground. As sensor 30 is attached to the shank of patient 52 and sensor 34 is connected to the thigh of patient 52, the X, Y and Z axis readings from each sensor define a vector V that represents the orientation of the sensor on the shank or thigh, and the angle between the two resulting vectors represents the angle between the shank and thigh. The formula for determining the angle between two vectors V1 and V2 is:

$$\theta = \cos^{-1} (V1 \cdot V2) / (|V1| \times |V2|)$$

Where • indicates the dot product of the vectors and |V| indicates the magnitude of the vector.

[0035] Measuring only accelerations will give a reasonably accurate representation of knee flexion angle when

patient 52 is at rest, but will be less accurate when there is any motion. To improve the estimate of the actual knee angle, there are several different filtering techniques to remove signal noise and accelerations due to motions of the patient. A particularly good technique is to use the three axis gyroscopes incorporated in sensors 30 and 34 to detect the angular rotation rate of the shank and thigh of patient 52 when they are moving and use this data to correct the readings taken from the accelerometers. In the preferred embodiment, a Kalman filter is used to make this correction.

[0036] The Kalman filter is an algorithm which uses a time series of measurements to estimate the next expected state of the system based on the current and previous states. It produces a statistically optimal estimate of the actual state of the system based on the measurements, even when the measurements include noise. In the case of an accelerometer and gyroscope, the accelerometer will include noise components as a result of motion, while the gyroscope will drift over time. In short, the accelerometer will give a good indication of the direction of gravity (hence the angle of the limb in question) over a long period of time, while the gyroscope will give a good indication of a change in angle over a short period of time, but will become increasingly inaccurate over longer periods of time due to drift. The Kalman filter thus uses both measurements to arrive at a good estimate of the actual orientation of the sensors.

[0037] In the preferred embodiment, readings are taken from sensors 30 and 34 every 1/10 of a second. The three acceleration measurements (X, Y and Z axes) and three gyroscope rate measurements (X, Y and Z axes) from sensor 30 are passed through the Kalman filter calculation to arrive at an estimate of the current X, Y and Z angles of sensor 30, which provides a vector representing the orientation of sensor 30 with respect to gravity. Similarly, the three acceleration measurements and three gyroscope rate measurements from sensor 34 are passed through the Kalman filter calculation to arrive at an estimate of the current X, Y and Z angles of sensor 34 with respect to gravity. As described above, the angle between the two resulting vectors is easily calculated.

[0038] The mathematics of a Kalman filter are well known in the art. In the preferred embodiment, the Kalman filter calculation is reduced to the following:

$$\text{Rate} = \text{NewRate} - \text{Bias} \quad 1)$$

Where temporary value Rate is calculated as the latest gyroscope rate reading (NewRate) minus the most recently calculated Bias amount. Bias is initially set to 0 and is updated during each pass through the Kalman filter.

$$\text{Angle} = \text{Angle} + \text{DeltaT} \times \text{Rate} \quad 2)$$

Where temporary value Angle is the previous value of Angle plus the time interval since the last reading (DeltaT) times the new Rate calculated in step 1.

$$P[0][0] = P[0][0] + \text{DeltaT} \times (\text{DeltaT} \times P[1][1] - P[0][1] - P[1][0] + Q_angle)$$

$$P[0][1] = P[0][1] - \text{DeltaT} \times P[1][1]$$

$$P[1][0] = P[1][0] - \text{DeltaT} \times P[1][1]$$

$$P[1][1] = P[1][1] + \text{DeltaT} \times Q_bias \quad 3)$$

Where P[] [] is the covariance matrix, Q_angle and Q_bias are constants. This step updates the estimation error covariance.

$$K[0]=P[0][0]/(P[0][0]+R_Measure)$$

$$K[1]=P[1][0]/(P[0][0]+R_Measure) \quad 4)$$

Where constant R_Measure is used to update the Kalman gain matrix K.

$$\text{tempAngle}=\text{newAngle}-\text{Angle} \quad 5)$$

$$\text{Angle}=\text{Angle}+K[0]\times\text{tempAngle} \quad 6)$$

$$\text{Bias}=\text{Bias}+K[1]\times\text{tempAngle} \quad 7)$$

[0039] In these steps, the angle calculated during that previous pass through the Kalman filter is subtracted from the new reading of the angle from the accelerometer, newAngle to get tempAngle, the change in angle. This is adjusted by the Kalman gain K[0] calculated in the previous step to arrive at a new value of the estimated actual angle, Angle. Similarly, a new value for Bias is calculated by multiplying the Kalman gain K[1] by tempAngle.

$$P[0][0]=P[0][0]-K[0]\times P[0][0]$$

$$P[0][1]=P[0][1]-K[0]\times P[0][1]$$

$$P[1][0]=P[1][0]-K[1]\times P[1][0]$$

$$P[1][1]=P[1][1]-K[1]\times P[1][1] \quad 8)$$

[0040] As a final step of the Kalman filter, the values of the covariance matrix are updated based on the updated Kalman gain.

[0041] It can be seen from the above that each of the X, Y and Z axis measurements of the inertial sensor (newAngle) can be combined with the X, Y and Z axis measurements of the gyroscope (NewRate) to arrive at a best estimate of the actual magnitude of gravitational acceleration measured by the sensors with respect to each axis. Doing this for the data read from both of sensors 30 and 34 results in the two vectors from which the angle between the shank and thigh of patient 52 can be calculated, as described above. The data comprises the number of flexions, the degree of flexion and the maximum and minimum amount of flexion of the affected joint. The maximum and minimum flex angle achieved during each flex is important for the assessment of the patient's rehabilitation because it is important to get the joint fully straight as part of the recovery process.

[0042] This angle and temperature information read from the sensors may be presented to the caregiver in many different forms, one of which is graphically, as hereinafter described.

[0043] Data from the two temperature sensors is also processed by database and server 20 to calculate the difference in temperature measured by temperature sensor 36 and temperature sensor 32. This difference in temperature is meaningful to the caregiver in that an elevation of the temperature measured by temperature sensor 32, which is located near surgical incision 54, with respect to the basal temperature measured by temperature sensor 36, which is located separated from the surgical incision 54 by a great enough distance that the sensor 36 will not detect an elevated temperature at the incision, may be indicative of infection of surgical incision 54. Alternatively, a decrease in the temperature measured by temperature sensor 32 with respect to the basal temperature measured by temperature sensor 36 is

a good indication that the patient is applying ice to the surgical site, which is a desirable part of the rehabilitation protocol.

[0044] The absolute temperature measured by sensors 32 and 36 is also of clinical interest. A rise in basal temperature as measured by temperature sensor 36, which is removed a distance from surgical incision 54, could indicate body heating due to exercise in the case of a small temperature rise, or a system infection causing a fever in patient 52. Similarly, a fall in the absolute temperature of sensor 32 is likely indicative of icing of the knee joint. Therefore, although there are advantages to considering the temperature differences between sensors 32 and 36, either sensor can provide useful information by itself.

[0045] The duration of temperature measured by sensor 32 is of clinical value as well and is data that is collected and analyzed by the present invention. As an example, if the absolute temperature measured by sensor 32 is indicative of the patient icing the joint, then determining the time that the temperature is indicative of icing allows the caregiver to know how long the patient is icing the joint.

[0046] FIG. 5 shows one of many possible ways to display the data obtained from patient worn sensors 10 as processed by database and server 20. In this graphical representation, vertical lines 60 indicate a knee flexion. The height of the line is proportional to the degree of flexion as indicated on the vertical axis. Thus a caregiver can easily determine the degree of activity, number of times the patient has flexed their knee and by what amount.

[0047] Line 62 shows the temperature difference between temperature sensors 32 and 36. In the figure, two periods of decreased temperature would indicate to the caregiver that the patient is properly icing their knee. To the right end of the temperature curve, there is a sharp and steady rise in the temperature difference. This would indicate to the caregiver the onset of infection. In this embodiment, the temperature differential is shown, however it is clear that similarly useful information can be conveyed by showing the absolute temperature measured by either or both sensors and the duration of time either or both of the sensors 32 and 36 remain at a given temperature or temperature range.

[0048] As the connection between remote computer 24 is connected to local computer 16 via Internet connections 22 and 18 is bi-directional, it is possible for the caregiver to interact with patient 52 using email, text messaging, or video chat using any number of easily available Internet communications tools. In the preferred embodiment, this communications was facilitated using the Claris Companion Android app from Claris Healthcare Inc. (www.clariscpanion.com). The Claris Companion app was integrated with the database and server of the preferred embodiment to add additional useful information to the graphical display of data for the caregiver, as well as to provide additional useful functions. For example, the Claris Companion app is configured to allow patient 52 to voluntarily provide a "pain score" from 1-10, where 1 is no pain at all and 10 is excruciating. Pain scores 64 are displayed along the time axis in FIG. 5 so that the caregiver can correlate the pain score with activity or temperatures. In addition, the Claris Companion app is configured to report whenever the patient chooses to take pain medication, as indicated by marks 66 in FIG. 5.

[0049] In addition to the manual communication between the caregiver and patient 52 made possible by the present

invention, the preferred embodiment provides automated coaching and encouragement to patient 52 via local computer 16. For example, the caregiver can set goals for patient 52 such as completing 25 repetitions of a knee flex beyond 80 degrees. When database and server 20 calculates that the target repetitions are completed by analyzing the data from patient worn sensors 10, it causes local computer 16 to display a congratulatory message. Similarly, analysis of the temperature data from patient worn sensors 10 can cause local computer 16 to show a confirmation message when patient 52 successfully lowers the temperature of surgical incision 54 by a desired amount, and can then start an on-screen timer to indicate how long the lowered temperature should be maintained. Further automated or manual coaching and encouragement can be provided in the form of instructional videos or photographs, encouraging messages, social interaction with similar patients, and 'gamification' in the form of goals, rewards and progress reporting.

[0050] FIG. 6 illustrates an alternative sensing means for determining the degree of flexion of the knee of patient 52. In this embodiment, distal motion sensor 30 is replaced with capacitive flex sensor 70, which in the preferred embodiment is a Soft Silicon Bend Sensor (bendlabs.com) that provides a signal proportional to the angle of flexion of sensor 70. Flex sensor 70 is an elongate strip attached to the leg of patient 52 so that the strip extends above, over and below the knee joint using anchor 72 and the case that encloses sensors 36 and 34. As sensor 70 provides a signal directly proportional to the degree of flexion of the knee of patient 52, there is no need to perform mathematical calculations to determine the flexion angle. Although no longer used in the calculation of the flexion angle, motion sensor 34 is retained in order to allow the orientation of the thigh of patient 52 to be measured. Knowing this orientation allows a caregiver to determine the body position of patient 52 while they are flexing their knee. For example, should motion sensor 34 indicate that the thigh of patient 52 is horizontal while the knee is flexed, it would indicate that patient 52 is performing the exercise while sitting, while if motion sensor 34 indicates that the thigh of patient 52 is vertical, it would indicate that the exercise is being performed while standing. Thus, data corresponding to the orientation of the limb that is proximate to the joint relative to a ground plane (i.e., a horizontal reference plane) is an effective in monitoring rehabilitation therapy.

[0051] Many variations on the preferred embodiment described here can be easily imagined. For example, although the invention as herein described is shown as used for a knee joint, it can easily be extended to operate in a similar fashion for any other joint on which surgery may be performed. The sensors described are one choice of many possibilities for measuring joint motion and temperature, and the choice of a data logger with local memory and periodic uploading could be eliminated in favour of real-time transfer of data from sensors 10 to local computer 16. Furthermore, it is possible to eliminate the cable and I2C bus by having each sensor connected to a separate Bluetooth radio linked to the local computer. It is also clear that there are other mathematical techniques for filtering data from accelerometers and gyroscopes to improve their accuracy and extracting the angle between sensors 30 and 34, many of which could provide equally useful measurements.

[0052] While the present invention has been described in terms of preferred and illustrated embodiments, it will be

appreciated by those of ordinary skill that the spirit and scope of the invention is not limited to those embodiments, but extend to the various modifications and equivalents as defined in the appended claims.

1. A method for detecting and monitoring movement of a post-surgical patient's limbs after surgery on a joint located between the limbs at a surgical site, the method comprising the steps of:

- a) attaching a first motion sensor to the patient's limb distal to the joint;
- b) attaching a second motion sensor to the patient's limb proximate to the joint;
- c) using the first and second motion sensors to detect the number of times the patient has flexed the joint;
- d) for each flexion of the joint, using the first and second motion sensors to detect the maximum and minimum flex angle of the joint by determining the angular orientation between the limb distal to the joint relative to the limb proximate to the joint during flexion;
- e) attaching a first temperature sensor to the patient at a first location near the surgical site; and
- f) attaching a second temperature sensor to the patient's limb at a second location that is spaced away from the surgical site so that the second temperature sensor detects a skin temperature that is not effected by the temperature of the patient's skin at the first location.

2. The method according to claim 1 including measuring the patient's skin temperature at the first and second locations and determining the difference in skin temperature between the first and second locations.

3. The method according to claim 2 including making a determination based upon the difference in skin temperature between the first and second locations regarding the condition of the surgical site.

4. The method according to claim 3 wherein the step of making a determination based upon the difference in skin temperature at the first and second locations comprises determining whether the difference in skin temperature is indicative of infection at the surgical site.

5. The method according to claim 3 wherein the step of making a determination based upon the difference skin temperature at the first and second locations comprises determining whether the difference in skin temperature is indicative of icing at the surgical site.

6. The method of claim 1 in which step c) further comprises the steps of:

- a) for each of the first and second motion sensors, measuring three acceleration measurements and three gyroscopic rate measurements;
- b) using the results from the measurement of three acceleration measurements and three gyroscopic rate measurements to assign a first vector value for the first motion sensor and a second vector value for the second motion sensor, wherein the vector value for the first motion sensor represents the orientation of the first motion sensor on the limb distal to the joint and the vector value for the second motion sensor represents the orientation of the second motion sensor on the limb proximate to the joint; and
- c) determining the number of times the joint is flexed.

7. The method according to claim 6 further comprising the step of for, each flexion of the joint, determining an angle between the first and second vector values wherein the angle

between the first and second vector values represents the angle of flexion between the limb distal to the joint and the limb proximate to the joint.

8. The method according to claim 7 including the step of displaying graphically the number of times the joint has flexed, and for each flex of the joint, the degree of flexion.

9. The method according to claim 8 including displaying graphically the maximum and minimum flex angle of the joint for each flex.

10. The method according to claim 3 including the step of displaying graphically the difference in skin temperature between the first and second locations.

11. The method according to claim 1 in which the number of times that the joint has flexed defines a first characteristic, the angle of flexion defines a second characteristic, and including the steps of:

- a) allowing a user to set a first target value for the first characteristic;
- b) allowing a user to set a second target value for the second characteristic; and
- c) comparing the number of times the joint has been flexed to the first target value; and
- d) comparing the angle of flexion between the limb distal to the joint and the limb proximate to the joint to the second target value.

12. The method according to claim 11 including causing a message to be displayed on a computer indicating that the first or second target value has been reached.

13. The method according to claim 1 in which the temperature at the first location defines a first characteristic, and the duration of temperature at the first location defines a second characteristic, and based on the first and second characteristics, making a determination if icing of the joint is occurring.

14. The method according to claim 1 including the step of determining the orientation of the patient's limb proximate to the joint relative to a ground plane.

15. A method for detecting and monitoring movement of a post-surgical patient's limbs after surgery on a joint located between the limbs at a surgical site, the method comprising the steps of:

- a) attaching a first motion sensor to the patient's limb distal to the joint;
- b) attaching a second motion sensor to the patient's limb proximate to the joint;
- c) attaching a first temperature sensor to the patient at a first location near the surgical site;
- d) attaching a second temperature sensor to the patient's limb at a second location that is spaced away from the surgical site so that the second temperature sensor detects a skin temperature that is not effected by the temperature of the patient's skin at the first location; and
- e) measuring the patient's skin temperature at the first and second locations and determining the difference in skin temperature between the first and second locations.

16. The method according to claim 15 including the step of determining whether the difference in the patient's skin temperature between the first and second locations is indicative of infection at the surgical site.

17. The method according to claim 16 including the step of determining whether the difference in the patient's skin temperature between the first and second locations is indicative of icing at the surgical site.

18. A method for detecting and monitoring movement of a post-surgical patient's limbs after surgery on a joint located between the limbs at a surgical site, the method comprising the steps of:

- a) attaching a sensor to the patient for measuring the angle between the patient's limb proximate to the joint and distal to the joint;
- b) determining the orientation of the patient's limb proximate to the joint relative to a horizontal ground plane.

19. The method according to claim 18 in which step a) further comprises the steps of attaching a first motion sensor to the patient's limb proximate to the joint.

20. The method according to claim 18 in which step a) further comprises the steps of:

- a) attaching a capacitive flex sensor strip to the patient such that the strip extends from a point distal to the joint, over the joint, and to a point proximate to the joint.

21. The method according to claim 19 including measuring the patient's skin temperature at the surgical site from a first location, measuring the patient's skin temperature at a second location that is separated from the first location, determining the difference in the measured temperatures from the first and second locations, and based upon the difference in the measured temperatures, making a determination about the condition of the surgical site.

22. A method for detecting and monitoring movement of a post-surgical patient's limbs after surgery on a joint located between the limbs at a surgical site, the method comprising the steps of:

- a) attaching a sensor to the patient for measuring the angle between the patient's limb proximate to the joint and distal to the joint;
- b) using the motion sensor to detect the number of times the patient has flexed the joint;
- c) for each flexion of the joint, detecting the maximum and minimum flex angle of the joint by determining the angular orientation between the limb distal to the joint relative to the limb proximate to the joint during flexion;
- d) attaching a first temperature sensor to the patient at a first location near the surgical site so that the first temperature sensor measures the skin temperature near the surgical site; and
- e) monitoring the temperature at the first location.

23. The method according to claim 22 including attaching a second temperature sensor to the patient's limb at a second location that is spaced away from the surgical site so that the second temperature sensor detects a skin temperature that is not effected by the temperature of the patient's skin at the first location.

24. The method according to claim 22 including making a determination based upon the skin temperature at the first location regarding the condition of the surgical site.

25. The method according to claim 24 wherein the step of making a determination based upon the skin temperature at the first location comprises determining whether the skin temperature is indicative of infection at the surgical site.

26. The method according to claim 24 wherein the step of making a determination based upon the skin temperature at the first location comprises determining whether the skin temperature is indicative of icing at the surgical site.

专利名称(译)	用于监测关节外科康复的装置和方法		
公开(公告)号	US20170265800A1	公开(公告)日	2017-09-21
申请号	US15/070341	申请日	2016-03-15
[标]申请(专利权)人(译)	CLARIS HEALTHCARE		
申请(专利权)人(译)	CLARIS HEALTHCARE INC.		
当前申请(专利权)人(译)	CLARIS HEALTHCARE INC.		
[标]发明人	AUCHINLECK GEOF SHARMAN PAUL FLETCHER STEFAN		
发明人	AUCHINLECK, GEOF SHARMAN, PAUL FLETCHER, STEFAN		
IPC分类号	A61B5/00 A61B5/01 A61B5/11 A61B5/107		
CPC分类号	A61B2562/0219 A61B5/4528 A61B5/1071 A61B5/01 A61B5/4833 A61B5/7275 A61B5/11 A61B5/6828 A61B5/742 A61B5/1121 A61B5/4585 A61B5/4848 G16H40/63 G16H50/20		
外部链接	Espacenet USPTO		

摘要(译)

运动传感器附接到远离已经发生手术的关节的患者肢体，并且另一运动传感器附接到靠近关节的肢体。在优选实施例中，运动传感器是加速度计和陀螺仪，其能够产生对应于关节屈曲的数据。温度传感器在关节处的手术部位处和在与手术部位分离的部位处附接到患者，从而可以监测传感器之间的温差。来自传感器的数据用于监测患者的手术后状况和康复情况，并向患者提供反馈。

