United States Patent Application Publication · 20250248650
Kind Code · A1
Publication Date · August 07, 2025
Inventor(s) · DeCerce; Joseph et al.

MEDICAL SENSOR AND METHOD

Abstract

A medical sensor is disclosed for mounting within a medical device. In one embodiment, more than one medical sensor is mounted to a printed circuit board using surface mount technology to accurately place the medical sensors in predetermined positions. The medical sensor is a sensor for measuring a force, pressure, or load. The medical sensor is manufactured in a process that supports consistency, matching, reliability, and performance. The medical sensor comprises a substrate, a dielectric layer overlying the substrate, and four strain gauges overlying the dielectric layer. Interconnect and pads are formed overlying the dielectric layer. The interconnect couples the four strain gauges into a full bridge Poisson gauge and couples the pads to the full bridge Poisson gauge. The active strain gauges are placed in a predetermined location on the substrate that support measurement of a force, pressure, or load applied to the substrate.

Inventors:	**DeCerce; Joseph (Fort Lauderdale, FL), Hazin; Wael (Plantation, FL)**
Applicant:	**HOWMEDICA OSTEONICS CORP.** (Mahwa, NJ)
Family ID:	**74798019**
Assignee:	**HOWMEDICA OSTEONICS CORP. (Mahwa, NJ)**
Appl. No.:	**19/189401**
Filed:	**April 25, 2025**

Related U.S. Application Data

parent US continuation 17158126 20210126 parent-grant-document US 12303290 child US 19189401
us-provisional-application US 62966375 20200127

Publication Classification

Background/Summary

FIELD
[0001] The present invention pertains generally to medical devices, and particularly to, but not exclusively to, a medical sensor for generating sensor data.
BACKGROUND
[0002] The skeletal system of a mammal is subject to variations among species. Further changes can occur due to environmental factors, degradation through use, and aging. An orthopedic joint of the skeletal system typically comprises two or more bones that move in relation to one another. Movement is enabled by muscle tissue and tendons attached to the skeletal system of the joint. Ligaments hold and stabilize the one or more joint bones positionally. Cartilage is a wear surface that prevents bone-to-bone contact, distributes load, and lowers friction.
[0003] There has been substantial growth in the repair of the human skeletal system. In general, orthopedic joints have evolved using information from simulations, mechanical prototypes, and patient data that is collected and used to initiate improved designs. Similarly, the tools being used for orthopedic surgery have been refined over the years but have not changed substantially. Thus, the basic procedure for repair of the musculoskeletal system has been standardized to meet the general needs of a wide distribution of the population. Although the tools, procedure, and artificial joints meet a general need, each procedure is subject to significant variation from patient to patient. The correction of these individual variations relies on the skill of the surgeon to adapt and fit the replacement joint using the available tools to the specific circumstance. It would be of benefit if quantitative measurement data is incorporated with the subjective skills of the surgeon.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
[0004] Various features of the system are set forth with particularity in the appended claims. The embodiments herein, can be understood by reference to the following description, taken in conjunction with the accompanying drawings, in which:
[0005] FIG. **1** is an illustration of a portion of a medical device in accordance with an example embodiment;
[0006] FIG. **2** is an illustration of a medical sensor for surface mounting in a medical device in accordance with an example embodiment;
[0007] FIG. **3** is an illustration of the configuration of the medical sensor in accordance with an example embodiment;
[0008] FIG. **4** is an illustration of the medical sensor coupled to a portion of a medical device in accordance with an example embodiment;
[0009] FIG. **5** is an illustration of a force, pressure, or load applied to the medical sensor in accordance with an example embodiment;
[0010] FIG. **6** is an illustration of the substrate of the medical sensor showing strain in accordance with an example embodiment;

[0011] FIG. **7** is a block diagram for forming one or more of the medical sensors in accordance with an example embodiment;

[0012] FIG. **8** is a block diagram for forming one or more of the medical sensors in accordance with an example embodiment;

[0013] FIG. **9** is an illustration of a medical device in accordance with an example embodiment;

[0014] FIG. **10** is a cross-sectional view of the medical device illustrating the full bridge Poisson bridge coupled between a surface module and a structure in accordance with an example embodiment;

[0015] FIG. **11** is a block diagram of electronic circuitry in the measurement device in accordance with an example embodiment;

[0016] FIG. **12** is a block diagram of a system or a computer in accordance with an example embodiment; and

[0017] FIG. **13** is an illustration of a communication network for measurement and reporting in accordance with an exemplary embodiment.

DETAILED DESCRIPTION

[0018] The following description of exemplary embodiment(s) is merely illustrative in nature and is in no way intended to limit the invention, its application, or uses.

[0019] Processes, techniques, apparatus, and materials as known by one of ordinary skill in the art may not be discussed in detail but are intended to be part of the enabling description where appropriate.

[0020] While the specification concludes with claims defining the features of the invention that are regarded as novel, it is believed that the invention will be better understood from a consideration of the following description in conjunction with the drawing figures, in which like reference numerals are carried forward.

[0021] The example embodiments shown herein below of the device are illustrative only and do not limit use for other parts of a body or for other applications. The device is used to measure at least parameter to generate quantitative measurement data. The device can be used on the knee, hip, ankle, spine, shoulder, hand, wrist, foot, fingers, toes, bone, muscle, ligaments tendon and other areas of the musculoskeletal system. In general, the principles disclosed herein are meant to be adapted for use in other locations of the musculoskeletal system. The following description of embodiment(s) is merely illustrative in nature and is in no way intended to limit the invention, its application, or uses.

[0022] For simplicity and clarity of the illustration(s), elements in the figures are not necessarily to scale, are only schematic and are non-limiting, and the same reference numbers in different figures denote the same elements, unless stated otherwise. Additionally, descriptions and details of well-known steps and elements are omitted for simplicity of the description. Notice that once an item is defined in one figure, it may not be discussed or further defined in the following figures.

[0023] The terms "first", "second", "third" and the like in the Claims or/and in the

[0024] Detailed Description are used for distinguishing between similar elements and not necessarily for describing a sequence, either temporally, spatially, in ranking or in any other manner. It is to be understood that the terms so used are interchangeable under appropriate circumstances and that the embodiments described herein are capable of operation in other sequences than described or illustrated herein.

[0025] Processes, techniques, apparatus, and materials as known by one of ordinary skill in the art may not be discussed in detail but are intended to be part of the enabling description where appropriate.

[0026] The orientation of the x, y, and z-axes of rectangular Cartesian coordinates is assumed to be such that the x and y axes define a plane at a given location, and the z-axis is normal to the x-y plane. The axes of rotations about the Cartesian axes of the device are defined as yaw, pitch and roll. With the orientation of the Cartesian coordinates defined in this paragraph, the yaw axis of

rotation is the z-axis through body of the device. Pitch changes the orientation of a longitudinal axis of the device. Roll is rotation about the longitudinal axis of the device. The orientation of the X, Y, Z axes of rectangular Cartesian coordinates is selected to facilitate graphical display on computer screens having the orientation that the user will be able to relate to most easily. Therefore the image of the device moves upward on the computer display whenever the device itself moves upward for example away from the surface of the earth. The same applies to movements to the left or right.

[0027] Although inertial sensors are provided as enabling examples in the description of embodiments, any tracking device (e.g., a GPS chip, acoustical ranging devices, an accelerometer, a magnetometer, a gyroscope, an inclinometers, and MEMs devices) can be used within the scope of the embodiments described.

[0028] At least one embodiment is directed to a kinetic orthopedic measurement system to aid a surgeon in determining real time alignment, range of motion, loading, impingement, and contact point of orthopedic implants. Although the system is generic to any orthopedic surgery (e.g., spinal, shoulder, knee, hip, ankle, wrist, finger, toe, bone, musculoskeletal, etc.) the following examples deal with orthopedic surgery as a non-limiting example of an embodiment of the invention.

[0029] The non-limiting embodiment described herein is related to quantitative measurement based orthopedic surgery and referred to herein as the kinetic system. The kinetic system includes a sensor system that provides quantitative measurement data and feedback that can be provided visually, audibly, or haptically to a surgeon or surgical team. The kinetic system provides the surgeon real-time dynamic data regarding force, pressure, or loading on the joint, bone, or musculoskeletal system, contact and congruency through a full range of motion, and information regarding impingement.

[0030] In general, kinetics is the study of the effect of forces upon the motion of a body or system of bodies. Disclosed herein is a system for kinetic assessment of the musculoskeletal system. The kinetic system can be for the installation of prosthetic components or for monitoring and assessment of permanently installed components to the musculoskeletal system. For example, installation of a prosthetic component can require one or more bone surfaces to be prepared to receive a device or component. The kinetic system is designed to take quantitative measurements of at least the load, position of load, or alignment with the forces being applied to the joint similar to that of a final joint installation. The sensored measurement components are designed to allow ligaments, tissue, and bone to be in place while the quantitative measurement data is taken. This is significant because the bone cuts take into account the kinetic forces where a kinematic assessment and subsequent bone cuts could be substantial changed from an alignment, load, and position of load once the joint is reassembled.

[0031] A prosthetic joint installation can benefit from quantitative measurement data in conjunction with subjective feedback of the prosthetic joint to the surgeon. The quantitative measurements can be used to determine adjustments to bone, prosthetic components, or tissue prior to final installation. Permanent sensors can also be housed in final prosthetic components to provide periodic data related to the status of the implant. Data collected intra-operatively and long term can be used to determine parameter ranges for surgical installation and to improve future prosthetic components. One or more sensors used post-operatively can be used to monitor motion of the musculoskeletal system to determine how the repair is performing and provide feedback based on quantitative measurement data. The physical parameter or parameters of interest can include, but are not limited to, measurement of alignment, load, force, pressure, position, displacement, density, viscosity, pH, spurious accelerations, color, movement, chemical composition, particulate matter, structural integrity, and localized temperature. Often, several measured parameters are used to make a quantitative assessment. A graphical user interface can support assimilation of measurement data. Parameters can be evaluated relative to orientation, alignment, direction, displacement, or position as well as movement, rotation, or acceleration along an axis or combination of axes by

wireless sensing modules or devices positioned on or within a body, instrument, appliance, vehicle, equipment, or other physical system.

[0032] At least one embodiment is directed to a system for trialing or permanently installing a prosthetic joint within the musculoskeletal system for stability, alignment, balance, and range of motion using quantitative measurement data. Monitoring the prosthetic joint with one or more sensors can be used for measuring parameters related to rehabilitation, infection, pain, reliability, performance, or wear. The prosthetic joint has at least one prosthetic component having an articular surface configured to support movement of the prosthetic joint. In one embodiment, the prosthetic component will have a plurality of strain gauge sensors underlying the articular surface and a position measurement system. The prosthetic component is configured to measure position, load magnitude, position of applied load, slope, rotation, range of motion, or movement. In one embodiment, a remote system is configured to wirelessly receive quantitative measurement data from the sensored prosthesis such that the remote system is configured to display parameters measured by the one or more sensors.

[0033] Embodiments of the invention are broadly directed to measurement of physical parameters. Many physical parameters of interest within physical systems or bodies can be measured by evaluating changes in resistance as a structure is under strain. As one example, a strain gauge can be placed on a structure that is under a variable load. The structure deforms under the load thereby changing the resistance of the strain gauge as it deforms with the structure. The physical parameter or parameters of interest can include, but are not limited to, measurement of load, force, pressure, displacement, density, viscosity, localized temperature. These parameters can be evaluated by measuring changes in the resistance of a strain gauge relative to orientation, alignment, direction, or position as well as movement, rotation, or acceleration along an axis or combination of axes by wireless sensing modules or devices positioned on or within a body, instrument, appliance, vehicle, equipment, or other physical system.

[0034] In all of the examples illustrated and discussed herein, any specific materials, temperatures, times, energies etc . . . for process steps or specific structure implementations should be interpreted to be illustrative only and non-limiting. Processes, techniques, apparatus, and materials as known by one of ordinary skill in the art may not be discussed in detail but are intended to be part of an enabling description where appropriate.

[0035] Note that similar reference numerals and letters refer to similar items in the following figures. In some cases, numbers from prior illustrations will not be placed on subsequent figures for purposes of clarity. In general, it should be assumed that structures not identified in a figure are the same as previous prior figures.

[0036] In the present invention these parameters are measured with an integrated wireless sensing module or device comprising an i) encapsulating structure that supports sensors and contacting surfaces and ii) an electronic assemblage that integrates a power supply, one or more sensors, one or more strain gauges, transducers, one or more inertial sensors, antennas and electronic circuitry that processes measurement data as well as controls all operations of energy conversion, propagation, and detection and wireless communications. The wireless sensing module or device can be positioned on or within, or engaged with, or attached or affixed to or within, a wide range of physical systems including, but not limited to instruments, appliances, vehicles, equipments, or other physical systems as well as animal and human bodies, for sensing and communicating parameters of interest in real time.

[0037] While the present invention has been described with reference to particular embodiments, those skilled in the art will recognize that many changes may be made thereto without departing from the spirit and scope of the present invention. Each of these embodiments and obvious variations thereof is contemplated as falling within the spirit and scope of the invention.

[0038] In the example of a prosthetic joint can be optimized using quantitative measurement data from one or more sensors. The patient can be monitored after being released from surgery and

during rehabilitation using sensor technology. The measurement data can support optimization of therapy and indicate problems that may occur. The effects of the therapy program using the intelligent prosthetic components can be linked to proper joint function and the patient can be educated on their recovery relative to their specific plan and compared with data from other patients. In one embodiment, when the prosthesis is activated, the data will be transmitted (RF/Bluetooth) to a patient recovery application. In one embodiment, the application can be on a computer or a device such as a smart phone. The quantitative measurement data from the sensors will be uploaded into a cloud based VPN (virtual private network) that is HIPPA Compliant. The quantitative measurement data can be assessed by one or more computer programs and updates, work flows, and the measurement data can be sent to the treating physician and health care team. The intelligent prosthesis can be used to support post-op exercises, treatment, or pharmaceuticals that can accelerate the healing phase. Furthermore, different reconstruction techniques can be compared with real-time data. Evaluations of the effects of reconstruction when combined with multi ligamentous injuries can also be analyzed. Healing phase monitoring related to graft adherence to the host tunnels (bone to bone, tendon to bone, composite to bone) can provide quantitative measurement data related thereto. Other important parameters can also be generated such as improving ROM and terminal extension, achieving improved muscle strength, improved proprioception, improved stability, and improved gait mechanics.

[0039] FIG. **1** is an illustration of a portion of a medical device **100** in accordance with an example embodiment. In general, medical device **100** includes one or more sensors, electronic circuitry, and a power source. Medical device **100** is configured to measure one or more parameters, control a measurement process, and transmit measurement data. More specifically, medical device **100** is designed for manufacturability where sensors and electronic components can be coupled to a printed circuit board **102** using surface mount technology or similar processes. The printed circuit board **102** can then be placed in a housing whereby the sensors align to the housing at predetermined locations to support measurement of the one or more parameters. Implementing an automated process improves performance, reduces variability, lower cost, and increases reliability of medical device **100**.

[0040] In one embodiment, medical device **100** is configured to measure a force, pressure or load applied to a housing. Sensor **104** is configured as a surface mount device that can be picked up, placed, and coupled to a printed circuit board **102** in an automated process. In the example, sensor **104** comprises a plurality of strain gauge sensors formed simultaneously as an integrated device. Forming the strain gauges simultaneously on sensor **104** allows each strain gauge to match each other to have equal or substantially equal performance characteristics. Pads **108**, **110**, **112**, and **114** are patterned and formed on a layer of sensor **104** to couple to corresponding pads on printed circuit board **102**. In the example, pads **108**, **110**, **112**, and **114** are soldered to corresponding pads on printed circuit board **102**. Electrical interconnect is also formed on the layer of sensor **104** that couple to pads **108**, **110**, **112**, and **114** and the plurality of strain gauges. Printed circuit board **102** can be a flexible printed circuit board or a rigid printed circuit board. Printed circuit board **102** can include one or more layers of interconnect configured to couple electronic components and sensors together to form a circuit.

[0041] FIG. **2** is an illustration of a medical sensor **116** for surface mounting in a medical device in accordance with an example embodiment. Medical sensor **116** is configured to measure a force, pressure, or load. Medical sensor **116** comprises a substrate **128**, a strain gauge **120**, a strain gauge **122**, a strain gauge **124**, and a strain gauge **126**. In one embodiment, a dielectric layer **138** overlies substrate **128**. Strain gauges **120**, **122**, **124**, and **126** overlie dielectric layer **138** and form a sensor array **118**. In one embodiment, strain gauges **120**, **122**, **124**, and **126** are formed simultaneously using photolithography to pattern and etch each device at the same time for superior device to device matching. Interconnect and pads **130**, **132**, **134**, and **136** are formed overlying dielectric layer **138**. The interconnect is patterned to couple strain gauges **120**, **122**, **124**, and **126** into a full

bridge Poisson gauge. The interconnect further couples inputs and outputs of the full bridge Poisson gauge to pads **130**, **132**, **134**, and **136** for surface mounting to a printed circuit board.

[0042] In one embodiment, a strain gauge comprises a resistive element. The resistive element is designed to conform to a substrate. The substrate is selected to elastically deform when a force, pressure, or load is applied. The strain gauge is coupled to the substrate such that the strain gauge is put under strain when the substrate elastically deforms. The deformation of the substrate applies a tensile or compressive strain such that the length or width of the resistive element is modified thereby resulting in a corresponding change in the resistance of the strain gauge. For example, the substrate is selected to elastically deform over an applied predetermined range of force, pressure, or load. The strain gauge is designed to provide a measurable resistance change over the applied predetermined range of force, pressure, or load. In one embodiment, the change in resistance is converted to a voltage. In one embodiment, the strain gauge can be used in a prosthetic component to measure loading in a range of 20 lbs. to 150 lbs. Ideally, the strain gauge operates linearly over the predetermined range of force, pressure, or load. Alternatively, the strain gauge can calibrated to reduce non-linearities over the predetermined loading range to provide accurate measurement.

[0043] In general, substrate **128** of medical sensor **116** is configured to elastically deform along the X-axis with little deformation along the Y-axis. The X and Y axis are shown on FIG. **2** and relate to a plane of the surface of substrate **128**. As illustrated strain gauges **122** and **124** are the active devices used to measure a resistance change when a force, pressure, or load is applied to substrate **128**. In other words, a force, pressure, or load applied to medical sensor **116** bends or deforms substrate **128** along the X-axis. The resistance of strain gauges **122** and **124** corresponds to the deformation of substrate **128**. The resistive element of the strain gauge is made to have substantial length in a first direction and a short length in a second direction. The substantial length of the resistive element is designed into the first direction to be responsive to the force, pressure, or load in changing the resistance. Conversely, the short length of the resistive element is designed to produce little change in the resistance in the second direction. Strain gauge **122** and strain gauge **124** are shown having substantial length along the X-axis while having a short length along the Y-axis. In one embodiment, the length of strain gauges **122** and **124** along the X-axis is increased by having multiple interconnected rows of the resistive element in series. This allows strain gauges **122** and **124** to have considerable length along the X-axis while having a compact shape that can fit within a predetermined area. Furthermore, the width of the resistive material used for strain gauges **122** and **124** are increased in the small lengths in the Y-axis direction to minimize resistance changes due to deformation. The increased width of strain gauges **122** and **124** along the Y-axis greatly reduces the resistance of strain gauge **122** and strain gauge **124** in the Y-axis direction thereby decreasing the sensitivity of measurement in the direction of the Y-axis. Thus, strain gauges **122** and **124** are designed to be sensitive in the X-axis direction while having reduced sensitivity in the Y-axis direction. In one embodiment, strain gauges **122** and **124** are placed in an area of substrate maximum deformation of medical sensor **116**.

[0044] Strain gauges **120**, **122**, **124**, and **126** are placed in a full bridge Poisson gauge configuration. Strain gauges **120** and **126** are non-active in the full bridge Poisson gauge configuration as they are oriented to measure deformation in the direction of the Y-axis. The full bridge Poisson gauge configuration will be discussed in more detail in FIG. **3**. In one embodiment, strain gauges **120**, **122**, **124**, and **126** are formed identical to one another. The orientation of strain gauges **120** and **126** are placed on substrate **128** having a substantial length along the Y-axis and a minimal length along the X-axis. In one embodiment, strain gauges **120** and **126** are placed at locations where low deformation or low strain occurs. In one embodiment, the length of strain gauges **120** and **126** along the Y-axis is increased by having multiple interconnected rows of the resistive element in series. This allows strain gauges **120** and **126** to have considerable length along the Y-axis while having a compact shape that can fit within a predetermined area. The width of the resistive material used for strain gauges **120** and **126** are increased in the small lengths in the

direction of the X-axis. The increased width of strain gauges **120** and **126** in the direction of the X-axis greatly reduces the resistance or change in resistance due to deformation of substrate **128**. In one embodiment, strain gauges **120** and **126** are identical to strain gauges **122** and **124** except for orientation to the X and Y-axis and location on substrate **128**. Thus, strain gauges **122** and **124** are sensitive to deformation of substrate **128** in the direction of the Y-axis while having reduced sensitivity to deformation of substrate **128** in the direction of the X-axis. In one embodiment, strain gauges **120**, **122**, **124**, and **126** can be premade strain gauges that are coupled by an adhesive to substrate **128**.

[0045] FIG. **3** is an illustration of the configuration of medical sensor **116** in accordance with an example embodiment. Components of FIG. **2** will be referred to in the explanation of a full bridge Poisson gauge **144** configuration. In one embodiment, strain gauges **120**, **122**, **124**, and **126** are coupled together to form full bridge Poisson gauge **144**. Strain gauge **120** has a first terminal coupled to node **148** and a second terminal coupled to node **150**. Strain gauge **122** has a first terminal coupled to node **150** and a second terminal coupled to node **152**. Strain gauge **126** has a first terminal coupled to node **152** and a second terminal coupled to node **154**. Strain gauge **124** has a first terminal coupled to node **154** and a second terminal coupled to node **148**.

[0046] In one embodiment, a voltage source **140** is coupled to full bridge Poisson gauge **144** to bias the circuit when used in medical sensor **116**. Voltage source **140** has a positive terminal coupled to node **150** and a negative terminal coupled to node **154**. A voltage output of the full bridge Poisson gauge **144** is provided at an output **146** and an output **142**. In one embodiment, output **146** and output **142** respectively correspond to a positive output and a negative output of the full bridge Poisson gauge **144**. In one embodiment, the positive terminal and the negative terminal of voltage source **140** couples respectively to pad **130** and pad **136** of medical sensor **116**. Pad **130** and pad **136** respectively correspond to node **150** and node **154** of the full bridge Poisson gauge **144**. In one embodiment, output **146** and output **142** of the full bridge Poisson gauge **144** couples respectively to pad **132** and pad **134**. Pad **132** and pad **134** respectively corresponds to node **148** and node **152** of full bridge Poisson gauge **144**. Thus, a voltage can be provided to pads **130** and **136** to bias full bridge Poisson gauge **144** and the output voltage measured across pads **132** and **134**. The output voltage measured across pads **132** and **134** corresponds to the force, pressure, or load applied to medical sensor **116**.

[0047] Placing a plurality of resistors in a bridge configuration as shown in FIG. **3** has been found to accurately measure unknown resistance. The bridge configuration also has been used to measure small changes in resistance. Strain gauges **120**, **122**, **124**, and **126** are variable resistors. In one embodiment, strain gauges **120**, **122**, **124**, and **126** are formed identically having the same resistance on substrate **128**. The only difference between strain gauges **120**, **122**, **124**, and **126** are the location on substrate **128** and the orientation of each strain gauge. Strain gauges **120**, **122**, **124**, and **126** couple to substrate **128** such that a force, pressure, or load applied to substrate **128** places a strain on one or more of the strain gauges that will change a resistance value that corresponds to the force, pressure, or load. The bridge configuration supports improved sensitivity, reduced noise, measurement stability, linearity of measurement, and reduced hysteresis. Medical sensor **116** is configured in a unique manner to support accurate, repeatable, and cost efficient force, pressure, or load sensing for medical applications. In one embodiment, medical sensor **116** is configured for being used in an automated process for building a prosthetic component that can measure loading applied by a musculoskeletal system. In one embodiment, a plurality of medical sensors **116** are used to measure loading applied by a musculoskeletal system to determine load magnitude of the applied load and position of applied load.

[0048] Referring briefly to FIG. **2**, substrate **128** is rectangular in shape. The X-axis is parallel to a long side of substrate **128**. The Y-axis is parallel to a short side of substrate **128**. Substrate **128** has a center point **160**. In one embodiment, medical sensor **116** is configured to measure a force, pressure, or load applied to center point **160**. The force, pressure, or load applied to substrate **128**

can comprise an area larger than depicted by center point **160** but the force, pressure, or load is directed to an area centered to or around center point **160**. In one embodiment, an origin of the X-axis and the Y-axis corresponds to center point **160**. Strain gauges **122** and **124** are the active devices of medical sensor **116**. Strain gauge **122** is above the X-axis but centered on the Y-axis. Strain gauge **124** is below the X-axis but centered on the Y-axis. Note that strain gauge **122** and strain gauge **124** are configured to measure strain or deformation of substrate **128** along or parallel to the X-axis.

[0049] In one embodiment, strain gauges **120** and **126** are non-active devices of medical sensor **116**. Strain gauge **120** is placed to the left of the Y-axis and strain gauge **126** is placed to the right of the Y-axis. In one embodiment, strain gauges **122** and **124** are placed physically closer to center point **160** than strain gauges **120** and **126**. Note that the strain gauges **120** and **126** are at least a distance of one half of the length or more of strain gauges **122** or **124** from center point **160**. Strain gauges **120 126** are aligned to measure strain or deformation the direction of the Y-axis.

[0050] As mentioned previously, strain gauges **122** and **124** are the active devices configured for measuring deformation or strain when a force, pressure, or load is applied to substrate **116**. In one embodiment, substrate **128** couples to a medical device such that a first end **162** and a second end **164** of substrate **128** of medical sensor **116** are supported. Applying a force, pressure, or load to an area around center point **160** will place substrate **128** under strain. Substrate **128** will elastically deform in the direction of the X-axis thereby changing the electrical resistance of strain gauges **122** and **124**. The elastic deformation of substrate **128** will deform strain gauges **122** and **124** in a manner that results in a change in resistance. Strain gauges **122** and **124** comprise resistive links in series to form a long resistive path in the direction of the X-axis. The resistive links are placed at or near center point **160** where a maximum deformation occurs. Thus, the sensitivity to change is increased in strain gauges **122** and **124** since the deformation will affect most or all the resistive links of each device. As shown, strain gauge **122** couples between node **150** and node **152** of full bridge Poisson gauge **144**. Node **150** couples to a positive terminal of voltage source **140**. Node **152** corresponds to output **142**. Strain gauge **124** couples between node **148** and node **154**. Node **154** couples to the node to a negative terminal of voltage source **140**. Node **148** couples to output **146**. As mentioned previously strain gauges **120** and **126** are non-active devices. Placing strain gauges **120** and **126** respectively near first end **162** and second end **164** of medical device **116** minimizes deformation applied to the devices. Moreover, the deformation occurs in the direction of the X-axis and strain gauges **120** and **126** are oriented to measure deformation or strain in the direction of the Y-axis. Thus, the resistance of strain gauges **120** and **126** should change little under deformation of substrate **128**.

[0051] In one embodiment, the resistance of strain gauges **120**, **122**, **124**, and **126** are greater than 10,000 ohms. The high resistance of strain gauges **120**, **122**, **124**, and **126** supports battery operation in a surgical environment where the time of use of medical device **116** can vary significantly. The resistance change in strain gauges **122** and **124** generates an output voltage across outputs **146** and **142** based on the force, pressure, or load applied to substrate **128**. For example, if strain gauges **120**, **122**, **124**, and **126** have identical resistances the voltage at output **142** and output **146** would be the same. Thus, the voltage measured across outputs **142** and **146** would be zero corresponding to a quiescent condition where no force, pressure, or load is applied to substrate **128**. In one embodiment, applying a force, pressure, or load to substrate **128** increases a resistance of strain gauges **122** and **124**. Assuming that strain gauges **122** and **124** are affected by the force, pressure, or load applied to substrate **128** equally due to the force, pressure, or load application at the center of substrate **128** and the symmetry of placement of strain gauges **120**, the change in resistance of strain gauges **122** and **124** would be substantially equal. Alternatively, the force, pressure, or load can applied across the entire width of substrate **128** in the direction of the Y-axis for a predetermined distance along the X-axis symmetrical about center point **160**.

[0052] Note that the placement of strain gauge **122** couples to the positive terminal of voltage

source **140** while strain gauge **124** couples to the negative terminal of the voltage source **140**. The divider network of full bridge Poisson gauge **144** is such that the changes in resistance of the active devices results in an additive measurable output voltage. A change in resistance of strain gauge **122** produces a corresponding change at output **142**. A change in resistance of strain gauge **124** produces a corresponding opposite change in voltage at output **148**. For example, an increase in resistance of strain gauges **122** and **124** will result in a reduction in voltage at output **142** and an increase in voltage at output **146** thereby resulting in a net voltage increase across outputs **146** and **142**. The increase across outputs **146** and **142** is twice the absolute voltage magnitude change across either strain gauge **122** or strain gauge **124** thereby increasing the sensitivity of measurement. Conversely, a decrease in resistance of strain gauges **122** and **124** will result in an increase in voltage at output **142** and a decrease in voltage at output **146** thereby resulting in a voltage decrease across outputs **146** and **142**. The decrease across outputs **146** and **142** is twice the absolute voltage magnitude change across either strain gauge **122** or strain gauge **124**. In one embodiment, the voltage output can be linear over the force, pressure, or load range. Alternatively, medical sensor **116** can be calibrated to remove non-linearities to measure accurately across the force, pressure, of load range.

[0053] FIG. **4** is an illustration of medical sensor **116** coupled to a portion of a medical device **174** in accordance with an example embodiment. A force, pressure, or load is applied to structure **170** of medical device **174**. In discussing medical device **174** the components of medical sensor **116** will be referred to as disclosed in FIG. **2**. Structure **170** couples to an area around center point **160** of substrate **128** of medical sensor **116**. In one embodiment, structure **170** is rectangular in shape and couples to an area of substrate **128** that corresponds to a location of strain gauges **122** and **124**. In one embodiment, structure **170** is placed on a side opposite from where strain gauges **122** and **124** reside such that structure **170** overlies strain gauges **122** and **124**. In one embodiment, structure **170** of medical device **170** couples to a first side of medical sensor **116** and strain gauges **120**, **122**, **124**, and **126** couple to a second side of medical sensor **116**.

[0054] A structure **172** of medical device **174** couples to the second side of medical sensor **116**. As mentioned previously, the second side of medical sensor **116** includes strain gauges **120**, **122**, **124**, and **126**. Structure **172** comprises a substrate **180**, a support **176**, and a support **178**. Supports **176** and **178** couple respectively to a first end **162** of medical sensor **116** and a second end **164** of medical sensor **116**. Supports **176** and **178** suspend medical sensor **116** above substrate **180** of medical device **174**. A force, pressure, or load applied to structure **170** of medical device **174** deforms substrate **128** of medical sensor **116** in a manner that creates strain in the direction of the X-axis and almost no strain in the direction of Y-axis. The force, pressure, or load applied to structure **170** causes substrate **128** to bow or deform towards substrate **180**. The deformation produces a resistance change in strain gauges **122** and **124** that is configured to be converted to a voltage measured by electronic circuitry within medical device **174**. The voltage output by medical sensor **116** corresponds to the force, pressure, or load applied to structure **170** of medical device **174**. In one embodiment, the voltage output by medical sensor **116** in a quiescent state where structure **170** is unloaded will be zero volts.

[0055] In one embodiment, structure **170** distributes a force, pressure, or load to the first side of medical sensor **116** across an entire width (in the direction of the Y-axis) of substrate **128**. Structure **170** is configured to distribute the force, pressure, or load approximately equal over the surface area of structure **170** coupling to substrate **128** of medical sensor **116**. Applying the force, pressure, or load in this manner minimizes any strain on substrate **128** in the direction of the Y-axis but maximizes strain on substrate **128** in the direction of the X-axis. Supports **176** and **178** respectively couple to first end **162** and second end **164** of substrate **128** on the second side across the entire width (in the direction of the Y-axis) of substrate **128**. Furthermore, strain gauges **120** and **126** reside outside regions of maximum strain on substrate **128** such that strain gauges **120** and **126** do not underlie structure **170** of medical device **174**. Strain gauges **120** and **126** are non-active because

medical sensor **116** is configured to produce no strain on substrate **128** of medical sensor **116** in the direction of Y-axis when a force, pressure, or load is applied to structure **170** of medical device **174**. Thus, the resistance of strain gauges **120** and **126** is configured not to change (or change very little) during a measurement of medical sensor **116** in the full bridge Poisson gauge **144** configuration.

[0056] FIG. **5** is an illustration of a force, pressure, or load **190** applied to medical sensor **116** in accordance with an example embodiment. FIG. **5** will refer to the elements or components of FIGS. **2-4**. The illustration is a side view of medical sensor **116** being suspended above substrate **180** by supports **176** and **178**. Medical sensor **116** is a part of medical device **174** configured for measuring force, pressure, or load **190**. In one embodiment, medical sensor **116** is configured to measure a force, pressure, or load **190** applied by a musculoskeletal system. In one embodiment, medical sensor is within a prosthetic component or device that is placed in the musculoskeletal system. In one embodiment, the force, pressure, or load **190** is applied to a structure **170** (not shown in FIG. **5**) of medical device **174** that couples to substrate **128** and overlies strain gauges **122** and **124** of medical sensor **116**. Force, pressure, or load **190** is applied central to substrate **128** in the X-axis and across the entire Y-axis. Force, pressure, or load **190** causes substrate **128** to elastically deform. In one embodiment, the maximum deformation will occur at the center of substrate **128** in the X direction. The strain on substrate **128** is indicated in FIG. **5** but shown in more detail in FIG. **6**. Note that the maximum strain occurs at along a center line **194** that couples through center **160** of substrate **128** of medical device **116**. In one embodiment, maximum deformation or strain is approximately equal on the center line **194**. Note that the strain decreases as you move farther away on either side from center line **194** on substrate **128**. In one embodiment, the strain is approximately symmetrical about center line **194** at equal distances from center line **194**. Increasing force, pressure, or load **190** will deform substrate **128** towards substrate **180** of medical device **174** thereby increases a resistance of strain gauges **122** and **124** of full bridge Poisson gauge **144** of medical sensor **116**. Conversely, reducing force, pressure, or load **190** will reduce deformation of substrate **128** thereby reducing resistance of strain gauges **122** and **124** of full bridge Poisson gauge **144**. Substrate **128** is configured to elastically deform under the force, pressure, or load. Substrate **128** is selected to elastically deform over a predetermined force, pressure, or load range.

[0057] FIG. **6** is an illustration of substrate **128** of medical sensor **116** showing strain in accordance with an example embodiment. In the example, a force, pressure, or load is applied to substrate **128** as disclosed herein above. As mentioned previously, medical sensor **116** is configured as a surface mount device for automatic pick and place to a printed circuit board. In the example, substrate **128** comprises 17-7 heat treated stainless steel. In one embodiment, substrate **128** is approximately 0.794 millimeters thick which is configured to handle loading of one hundred pounds or less. Substrate **128** can comprise a polymer, plastic, metal, or other elastically deformable material. The strain measured on substrate **128** is indicated in grey scale and the magnitude of strain is indicated in table **192**. Note that the strain on substrate **128** is approximately equal in the Y-direction over a small distance in the X-direction where the origin of the X axis and Y axis is at center **160** of substrate **128** as shown in FIG. **2**. Conversely, the strain changes on substrate **128** from a center line **194** of substrate **128** moving in the X-direction towards either first end **162** or second end **164** of substrate **128**. In the example, the change in strain is approximately symmetrical about the center line **194**. The measurement of the strain reduces from center line **194** to either first end **162** or second end **164** of substrate **128**. Note that the strain measured on substrate **128** where support **176** or support **178** of structure **172** (FIG. **4**) supports substrate **128** measures approximately zero. Substrate **128** supported by support structure **176** or support structure does not deform in the supported area. As mentioned previously, structure **170** of medical device **174** overlies strain gauges **122** and **124** but not strain gauges **120** and **126**. This configuration of medical sensor **116** supports automated placement within medical device **174** while supporting measurement by two

strain gauges per sensor for increased measurement sensitivity. In one embodiment, strain gauges **120**, **122**, **124**, and **126** are configured to have resistances of 10,000 ohms or above to support battery operation.

[0058] FIG. **7** is a block diagram **200** for forming one or more medical sensors **116** in accordance with an example embodiment. In block diagram **200**, the components and structure of medical sensor **116** of FIG. **2** and FIG. **3** will be referenced. In one embodiment, medical sensor **116** is configured to be manufactured as a surface mount device that can support an automated process of building a medical device, improved strain gauge matching, increased resistance for battery operation, reliability, performance, and lowering cost. In the example, medical sensor **116** is a full bridge Poisson strain gauge **144** comprising four strain gauges **120**, **122**, **124**, and **126** as shown in FIGS. **2** and **3**. The block diagram **200** discloses building an array of medical sensors **116** simultaneously and using an automated process to build a medical device having a plurality of medical sensors **116**.

[0059] In a step **202** an array of metal blanks are provided. The metal blanks comprise a plurality of substrates **128**. In one embodiment, each metal blank comprises 17-7 heat treated stainless steel in a predetermined size. In the example, each substrate is approximately 0.794 millimeters thick and configured to measure loading of approximately 100 lbs. In one embodiment, the metal blanks comprise a 4 inch by 4 inch array of 200 substrates **128**. The array is designed to support handling and processing steps for forming the plurality of medical sensors **116**. In a step **204**, dielectric material is formed over at least one surface of substrates **128** of the array.

[0060] The dielectric material is configured to couple to the plurality of substrates. In one embodiment, the dielectric material comprises polyamide. The dielectric material is a non-conductive layer configured to electrically isolate interconnect, pads, and strain gauges **120**, **122**, **124**, and **126** from a corresponding substrate **128**. In one embodiment, dielectric layer **138** can be deposited onto the array of substrates **128** simultaneously to form a uniform layer on each substrate **128**. The dielectric layer will also be uniform from substrate to substrate of the plurality of substrates **128**. Alternatively, a dielectric substrate can be attached to the array of substrates **128**. In one embodiment, an adhesive can be used to attach the dielectric substrate to the array of substrates **128**.

[0061] In a step **206**, a metal layer is applied to the array of substrates **128**. Metal is deposited or formed onto the plurality of substrates **128**. In one embodiment, the metal is formed overlying dielectric layer **138** on the plurality of substrates **128**. The metal layer can be copper, aluminum, an alloy, or other conductive metal. Alternatively, a non-metal conductive layer could also be used. In one embodiment, metal is sputtered to form the metal layer on substrates **128** of the array at the same time. The metal layer is used to form interconnect and pads overlying the array of substrates **128**. In a step **210**, the metal layer can be patterned using a laser to cut or remove metal. Alternatively, a patterning layer is formed overlying the metal layer to define the interconnect and pads. In one embodiment, the patterning layer can be photoresist to define protected areas where metal from the metal layer remains. An etchant is used to etch the metal not protected by the photoresist thereby leaving the patterned metal. In the example, each substrate of the array has patterned metal corresponding to interconnect and pads **130**, **132**, **134**, and **136**. A laser can also be used to cut or sever the metal blanks.

[0062] In a step **212**, the strain gauges are formed overlying the dielectric layer **138**. In one embodiment, the material used to form a strain gauge is a conductive material that will change resistance depending on an applied strain. In one embodiment, Nichrome is used to form strain gauges **120**, **122**, **124**, and **126**. Nichrome is an alloy of nickel and chromium that is commonly used as a resistance heating element. Nichrome will change resistance predictably under strain and can be formed into a strain gauge greater than 10K ohms for use in a battery operated medical device. Nichrome is deposited overlying the dielectric material. Similar to the process disclosed on patterning the metal to form interconnect and pads, the deposited Nichrome can be masked to

define strain gauges **120**, **122**, **124**, and **126** on each of the plurality of substrates **128**. In one embodiment, etchant is used to remove Nichrome. The masked areas are protected from the etchant thereby leaving strain gauges **120**, **122**, **124**, and **126** on dielectric layer **138**. The terminals of strain gauges **120**, **122**, **124**, and **126** are formed on corresponding metal interconnect. Nichrome formed on metal interconnect will form a contact or electrode that conducts electricity. As mentioned previously, the metal interconnect couples to strain gauges **120**, **122**, **124**, and **126** to form the full bridge Poisson gauge **144** as shown in FIG. **3**. The metal interconnect also couples to pads **130**, **132**, **134**, and **136** for coupling the full bridge Poisson gauge **144** for voltage bias and the measurement output. The array now comprises a plurality of medical sensors **116**. In one embodiment, the array of medical sensors **116** can be placed in a probing station for automated testing before being separated into individual medical sensors. No order is implied in the method. For example, strain gauges **120**, **122**, **124**, and **126** can be formed before metal is deposited overlying dielectric layer **138** on the plurality of substrates **128**. Strain gauges **120**, **122**, **124**, and **126** are formed as disclosed herein above. The metal can then be deposited, patterned, and etched to couple to strain gauges **120**, **122**, **124**, and **126** and to form interconnect and pads **130**, **132**, **134**, and **136**.

[0063] Medical sensors **116** are separated from one another and can be handled as a surface mount device. In an automated surface mount technology process, medical sensors **116** can be pick and placed to populate a printed circuit board. In one embodiment, medical sensors **116** are tested and placed in a tray or holder for surface mounting. In a step **216**, medical sensor **116** is precisely placed onto a printed circuit board such that pads **130**, **132**, **134**, and **136** are soldered to corresponding pads on the printed circuit board. Other components are populated on the printed circuit board during the surface mount process to form a circuit or system. In one embodiment, the circuit is configured to support a measurement process and transmit measurement data. In one embodiment, the printed circuit board is populated with two or more medical sensors **116** placed and coupled in predetermined locations on the printed circuit board.

[0064] In the step **216**, at least one of the full bridge Poisson gauges **144** are coupled to a printed circuit board using surface mount technology. Referring briefly to FIG. **1**, surface mount sensor **104** is shown coupling to printed circuit board **102**. In one embodiment, at least three of the full bridge Poisson gauges **144** are coupled to the printed circuit board. The printed circuit board has interconnect that couples one or more full bridge Poisson gauges **144** and electrical components into an operational circuit or system. In one embodiment, the operational circuit of printed circuit board is configured to control a measurement process of the full bridge Poisson gauges **144**. In one embodiment, the full bridge Poisson gauges **144** are configured to measure a load magnitude and a position of applied load. The operational circuit can be configured to transmit data from the full bridge Poisson gauges or other sensors coupled to the circuit. In a step **218**, the printed circuit board assembly is completed using surface mount technology. The components and full bridge Poisson gauges **144** are coupled to the printed circuit board. The printed circuit board assembly may be placed in a furnace to reflow the solder joints for electrical and mechanical coupling. The printed circuit board assembly can then be placed or mounted within medical device **174**.

[0065] FIG. **8** is a block diagram **220** for forming one or more medical sensors **116** in accordance with an example embodiment. In block diagram **220**, the components and structure of medical sensor **116** of FIG. **2** and FIG. **3** will be referenced. In one embodiment, medical sensor **116** is configured to be manufactured as a surface mount device that can support an automated process of building a medical device, improved strain gauge matching, increased resistance for battery operation, reliability, performance, and lowering cost. In the example, medical sensor **116** is a full bridge Poisson strain gauge **144** comprising four strain gauges **120**, **122**, **124**, and **126** of FIGS. **2** and **3**. The block diagram **220** discloses building an array of medical sensors **116** simultaneously and using an automated process to build a medical device having a plurality of medical sensors **116**.

[0066] In a step **222**, an array of metal blanks is provided. The metal blanks comprise a plurality of substrates **128**. In one embodiment, each metal blank comprises 17-7 heat treated stainless steel in a predetermined size. In the example, each substrate is approximately 0.794 millimeters thick and configured to measure loading of approximately 100 lbs. In one embodiment, the metal blanks comprise a 4 inch by 4 inch array of 200 substrates **128**. The array of metal blanks is designed to support handling and processing steps for forming the plurality of medical sensors **116**.

[0067] In a step **224**, a sheet of full bridge Poisson gauges are formed. The sheet of strain gauges are formed in a separate process to control the tolerances of the deposited strain gauge metal such that strain gauges **120**, **122**, **124**, and **126** will match more accurately as required in a medical device application. A substrate comprising a dielectric material is configured to couple to a sacrificial substrate. The sacrificial substrate is a substrate that is used to support performing processing steps on the dielectric material. In one embodiment, a polyamide substrate can be formed on or coupled to the sacrificial substrate. Polyamide is a dielectric material. The sacrificial substrate is used to support the polyamide substrate during the process of forming the strain gauges **120**, **122**, **124**, and **126**, interconnect, and pads **130**, **132**, **134**, and **136**. The sacrificial substrate can be glass, metal, a polymer, or other suitable material. In one embodiment, the dielectric material will not form a permanent or irreversible bond to the sacrificial substrate thereby supporting removal of the dielectric substrate from the sacrificial substrate. The sacrificial substrate is not used further in the process to manufacture medical sensor **116**. The sacrificial substrate may be disposed of or reused to support processing another substrate. Alternatively, strain gauges **120**, **122**, **124**, and **126** can be premade strain gauges. In one embodiment the premade strain gauges can be coupled to the sacrificial substrate.

[0068] In general, a plurality of full bridge Poisson gauges **144** (each comprising strain gauges **120**, **122**, **124**, and **126**, interconnect, and pads **130**, **132**, **134**, and **136**) are formed on the dielectric substrate and each full bridge Poisson gauge is configured to couple to a corresponding substrate **128** of plurality of substrates **128**. In one embodiment, Nichrome is sputtered onto, patterned, and etched on the dielectric substrate to form strain gauges **120**, **122**, **124**, and **126** as disclosed herein above. Similarly, the metal interconnect and pads **130**, **132**, **134**, and **136** can be deposited, patterned, and etched on the polyamide substrate in a different or separate step. Note that the plurality of full bridge Poisson gauges **144** are formed simultaneously as an array. In one embodiment, the metal interconnect and pads can be formed of copper, aluminum, a metal, a low resistance material, or an alloy. The metal is configured to couple to the Nichrome. No order is implied in the above mentioned steps as the Nichrome can be deposited, patterned, and etched before or after the metal is deposited, patterned, and etched. The polyamide substrate is then removed from the sacrificial substrate. Thus, polyamide substrate removed from the sacrificial substrate comprises a plurality of full bridge Poisson gauges **144** that corresponds to the plurality of substrates **128**. Each full bridge Poisson gauge **144** comprises strain gauges **120**, **122**, **124**, and **126**, interconnect, and pads **130**, **132**, **134**, and **136** configured for supporting surface mount technology. Alternatively, the premade strain gauges can be provided.

[0069] In a step **226**, the polyamide sheet is coupled to the array of metal blanks such that each full bridge Poisson gauge **144**, interconnect, and pads **130**, **132**, **134**, and **136** is aligned to a corresponding metal blank of the array of metal blanks. In one embodiment, an adhesive can be used to couple the polyamide sheet to the array of metal blanks. The polyamide substrate of the pre-manufactured sheet isolates or prevents electrical coupling of full bridge Poisson gauges **144**, interconnect, and pads **130**, **132**, **134**, and **136** to a corresponding metal blank (e.g. substrate **128**). An adhesive can be applied between the polyamide sheet and the array of metal blanks. In one embodiment, the array of metal blanks and the polyamide sheet are placed in an oven. The adhesive, polyamide sheet, and the array of metal blanks are heated for a predetermined time to cure the adhesive such that polyamide sheet couples to the array of metal blanks. In one embodiment, the adhesive is configured to match the expansion coefficient of the metal used in the

array of metal blanks. In a step **228**, the bonded blank can be handled after the adhesive is cured and comprises a plurality of full bridge Poisson gauges **144**. In a step **230**, medical sensors **116** are separated from one another. In one embodiment, medical sensors **116** can be laser cut, tested, calibrated, and loaded to be used in an automated surface mount technology system. In a step **232**, medical sensors **116** after being separated from one another can be placed in a tray for automated pick up, placement, and soldering of medical sensors **116** to a printed circuit board. In one embodiment, medical sensors **116** are full bridge Poisson gauge **144** comprising a metal such as Nichrome formed on a dielectric substrate that is bonded to a substrate **128** comprising metal. The metal substrate is configured to induce strain on the full bridge Poisson gauge **144** under load. The force, pressure, or load applied to the metal substrate relates to the resistance measured by full bridge Poisson gauge **144**. In one embodiment, the resistance of full bridge Poisson gauge **144** is converted to a voltage such that the voltage relates to the force, pressure, or load applied to the metal substrate. In an alternate embodiment, premade strain gauges can be coupled to the array of metal blanks. The premade strain gauges will have the orientation as shown in FIG. **2**.

[0070] In a step **234**, at least one of the full bridge Poisson gauges **144** are coupled to a printed circuit board using surface mount technology. Referring briefly to FIG. **1**, surface mount sensor **104** is shown coupling to printed circuit board **102**. In one embodiment, at least three of the full bridge Poisson gauges **144** are coupled to the printed circuit board. The printed circuit board has interconnect to couple full bridge Poisson gauges **144** and components in an operational circuit. In one embodiment, the operational circuit of printed circuit board is configured to control a measurement process of full bridge Poisson gauges **144**. In one embodiment, full bridge Poisson gauges **144** are configured to measure a load magnitude and a position of applied load at predetermined locations. The operational circuit can be configured to transmit data from the full bridge Poisson gauges or other sensors coupled to the circuit. In a step **236**, the printed circuit board assembly is completed using surface mount technology. The components and full bridge Poisson gauges **144** are coupled to the printed circuit board. The printed circuit board assembly may be placed in a furnace to reflow the solder joints for electrical and mechanical coupling. The printed circuit board assembly can then be placed or mounted within medical device **174**.

[0071] FIG. **9** is an illustration of a medical device **250** in accordance with an example embodiment. Medical device **250** is a device for measuring loading applied by the musculoskeletal system. Medical device **250** couples to the musculoskeletal system and can be a tool, equipment, device, or structure configured to measure an applied force, pressure, or load. In one embodiment, medical device **250** can be a module configured to couple to a tool, device, or prosthetic component to support a force, pressure, or load measurement. In the example, medical device **250** is a prosthetic component. More specifically, medical device **250** as shown is an insert of a knee prosthetic joint. The insert is a prosthetic component that couples between a femoral prosthetic component (coupled to a femur) and a tibial prosthetic component (coupled to a tibia). The condyles of the femoral prosthetic component couple to surfaces of the insert to support movement under musculoskeletal loading. In one embodiment, the insert is a trialing device. In one embodiment, medical device **250** is configured to measure loading applied by the musculoskeletal system on a medial side and a lateral side of a knee joint. The quantitative measurement data from medical device **250** as a trialing device is used to adjust parameters such loading, balance, and position of applied load on the medial and lateral sides of the insert. The quantitative measurement data is sent to a computer in view of a surgeon and surgical team that can be viewed in real-time as adjustments are made. Medical device **250** is removed after the measured parameters are within a predetermined range based on clinical evidence for a knee joint and a final insert (identical in shape and size) is fitted within the knee joint. In one embodiment, medical device **250** is used to support balancing the knee joint such that the loading applied to the medial and lateral side of the insert is at a predetermined ratio. Alternatively, medical device **250** can be integrated in a tool such as a knee tensor to provide position of applied load and load magnitude measurements or as a separate

module that can be placed in equipment for measurement purposes and then removed.

[0072] Reference to structure or elements in FIGS. **1-7** will be used to illustrate measuring force, pressure, or load in medical device **250**. Medical device **250** comprises a structure **252**, a structure **262**, surface module, **254**, surface module **258**, seal **256**, seal **260**, printed circuit board **270**, and full bridge Poisson gauges **264**, **266**, **268**, **272**, **274**, and **276**. Structure **252** and structure **262** couple together to form a housing of medical device **250** that is hermetically sealed. Surface module **254** and surface module **258** provide an articular surface for supporting knee motion as the knee joint is tested. Surface module **254** and surface module **258** couple to the condyles of the femur or the condyles of a femoral prosthetic component. Surface modules **254** and **258** fit within openings in structure **252**. O-ring **256** seals surface module **254** to structure **252** to maintain hermeticity of medical device **250**. Similarly, O-ring **260** seals surface module **258** to structure **252** to maintain hermeticity of medical device **250**. In one embodiment, O-rings **256** and **260** respectively support movement of surface module **254** and surface module **258** when loaded by the musculoskeletal system. The movement of surface modules **254** and **258** is needed flex the substrates of full bridge Poisson gauges **264**, **266**, **268**, **272**, **274**, or **276**.

[0073] Full bridge Poisson gauges **264**, **266**, and **268** couple to printed circuit board **270** and are configured to measure loading applied to surface module **254**. Full bridge Poisson gauges **264**, **266**, and **268** are placed at vertexes of a polygon. The position of full bridge Poisson gauges **264**, **266**, and **268** are known on printed circuit board **270** and relative to a surface of surface module **254**. Similarly, full bridge Poisson gauges **272**, **274**, and **276** couple to printed circuit board **270** and are configured to measure loading applied to surface module **258**. Full bridge Poisson gauges **272**, **274**, and **276** are placed at vertexes of a polygon. The position of full bridge Poisson gauges **272**, **274**, and **276** are known on printed circuit board **270** and relative to a surface of surface module **258**.

[0074] Electronic components couple to printed circuit board **270**. The electronic components are electrically coupled together using one or more layers of interconnect on or in printed circuit board **270** to form a circuit or system. In one embodiment, the system is configured to generate measurement data from one or more sensors coupled to the circuit and transmit the measurement data to a computer or interface that is separate from medical device **250**. In general, each full bridge Poisson gauge is configured to generate a load measurement. A computer receives the load magnitude at each location of the polygon and calculates a position of applied load on the surface of the corresponding surface module from the measurement data. The computer will also calculate the load magnitude at the position of applied load on the surface of the corresponding surface module. In one embodiment, medical device **250** can provide the measurement data in real-time to track changes in position of applied load and load magnitude over a range of motion.

[0075] Full bridge Poisson gauges **264**, **266**, **268**, **272**, **274**, and **276** are formed as described herein above as surface mount technology devices that supports accurate placement on printed circuit board **270** using an automated manufacturing process. Precise placement of full bridge Poisson gauges **264**, **266**, **268**, **272**, **274**, and **276** is important because printed circuit board **270** and full bridge Poisson gauges **264**, **266**, **268**, **272**, **274**, and **276** couple to structure **262**, surface module **254**, and surface module **258** at predetermined locations. Misalignment will result in inaccurate measurement results, reliability issues, or device failure. There are two or more alignment features on structure **262** that align and retain printed circuit board **270** to structure **262**. The placement of printed circuit board **270** to structure **262** aligns full bridge Poisson gauges **264**, **266**, **268**, **272**, **274**, and **276** to corresponding supports formed in structure **262** that suspends the sensors over a cavity to support flexing of the substrate under load. Thus, full bridge Poisson gauges **264**, **266**, **268**, **272**, **274**, and **276** are supported, aligned, and retained at predetermined locations of structure **262** and surface mounted to printed circuit board **270**.

[0076] Structure **252** aligns and couples to structure **262**. Surface module **254** fits within an opening in structure **252**. In one embodiment, surface module **254** has a retaining lip **280**. O-ring **256** is placed around surface module **254** and a portion of O-ring **256** is configured to be held in

place by retaining lip **280**. In one embodiment, surface module **254** will be stopped from being pushed further in the opening of structure **252** when O-ring **256** couples between retaining lip **280** and the corresponding lip on structure **252** within the opening. O-ring **256** will compress between structure **252** and surface module **254** to hermetically seal the opening in structure **252**. Furthermore, O-ring **256** supports movement of surface module **254** while maintaining the hermetic seal during an application of a force, pressure, or load to full bridge Poisson gauges **264**, **266**, and **268**. In one embodiment, a first region, a second region, and a third region extends from surface module **254** to couple respectively to full bridge Poisson gauges **264**, **266**, and **268**. In one embodiment, the first region, the second region, and the third region correspond to predetermined locations on the surface of surface module **254**. The predetermined locations are used in the calculation of the position of applied load and the load magnitude at the position of applied load. In one embodiment, the first, second, and third regions each have a predetermined area that is configured to couple respectively to predetermined areas of full bridge Poisson gauges **264**, **266**, and **268**.

[0077] Similarly, surface module **258** fits within an opening in structure **252**. In one embodiment, surface module **258** has a retaining lip **282**. O-ring **260** is placed around surface module **258** and a portion of O-ring **260** is configured to be held in place by retaining lip **282**. In one embodiment, surface module **258** is pushed within the opening in structure **252** until O-ring **260** couples to a corresponding retaining lip on structure **252**. In one embodiment, surface module **258** will be stopped from being pushed further in the opening of structure **252** when O-ring **260** couples between retaining lip **282** and the corresponding lip on structure **252** within the opening. O-ring **260** will compress between structure **252** and surface module **258** to hermetically seal the opening in structure **252**. Furthermore, O-ring **260** supports movement of surface module **258** while maintaining the hermetic seal during an application of a force, pressure, or load to full bridge Poisson gauges **272**, **274**, and **276**. In one embodiment, a first region, a second region, and a third region extends from surface module **258** to couple respectively to full bridge Poisson gauges **272**, **274**, and **276**. In one embodiment, the first region, the second region, and the third region correspond to predetermined locations on the surface of surface module **258**. The predetermined locations are used in the calculation of the position of applied load and the load magnitude at the position of applied load. In one embodiment, the first, second, and third regions of surface module **258** each have a predetermined area that is configured to couple respectively to predetermined areas of full bridge Poisson gauges **272**, **274**, and **276**. This will be disclosed in greater detail herein below.

[0078] FIG. **10** is a cross-sectional view of medical device **250** illustrating full bridge Poisson gauge **272** coupled between surface module **258** and structure **262** in accordance with an example embodiment. In particular, the cross-sectional view illustrates how the surface mounted full bridge Poisson gauge **272** is placed into medical device **250**. Surface mounted full bridge Poisson gauge **272** is equivalent to medical sensor **116** disclosed in FIGS. **2-6**. Referring briefly to FIG. **4**, substrate **128** having a sensor array **118** is coupled to medical device **174**. Substrate **128** is supported by support **176** and support **178** on a sensored side of substrate **128**. Structure **170** applies a force, pressure, or load to substrate **128** on a non-sensored side of substrate **128**. In one embodiment, structure **170** applies the force, pressure, or load to active strain gauges of the sensor array while the non-active strain gauges of the sensor array have minimal or no force, pressure, or load applied. Full bridge Poisson gauges **264**, **266**, and **268** of medical device **250** coupled between surface module **254** and structure **262** is coupled similar to sensor array **118** of FIG. **4**. Similarly, full bridge Poisson gauges **272**, **274**, and **276** coupled between surface module **258** and structure **262** is coupled similar to sensor array **118** of FIG. **4**. This is shown in detail for full bridge Poisson gauge **272** in the cross-sectional view discussed herein below.

[0079] Full bridge Poisson gauge **272** is surface mounted to printed circuit board **270**. Full bridge Poisson gauge **272** is supported by at a first end by support **284** of structure **262** and at a second

end by support **286** of structure **262**. One or more retaining features align and retain full bridge Poisson gauge **272** and printed circuit board **270** to structure **262**. Full bridge Poisson gauge **272** and a portion of printed circuit board **270** are suspended over a cavity **288** in structure **262**. Surface module **258** includes a region **292** that is configured to couple to full bridge Poisson gauge **272**. In one embodiment, region **292** couples to a non-sensored side of the substrate of full bridge Poisson gauge **272**. Region **292** of surface module **258** has a predetermined area configured to couple to a predetermined area of full bridge Poisson gauge **272**. In one embodiment, the predetermined area of region **292** relates to applying a force, pressure, or load to the active strain gauges of full bridge Poisson gauge **272**. In one embodiment, the predetermined area of region **292** does not overlie the non-active strain gauges of full bridge Poisson gauge **272**. O-ring **260** forms the hermetic seal between structure **252** and surface module **258**. Retaining lip **282** of surface module **258** and retaining lip **290** of structure **252** supports retention of O-ring **260** in a predetermined location. O-ring **260** comprises a compressible material such as PTFE, Neoprene, Rubber, Fluorocarbon, or silicone that supports movement of surface module **258** under the force, pressure, or load.

[0080] A force, pressure, or load applied to surface module **258** couples a portion of the force to full bridge Poisson gauge **272**. The remaining force, pressure, or load is applied to full bridge Poisson gauges **274** and **276**. The location of region **292** of surface module **258** corresponds to a predetermined location on the surface of surface module **258**. Electronic circuitry **292** coupled to printed circuit board **270** is configured to control a measurement process and transmit measurement data. In general, the measurement data is transmitted to a computer. The computer receives the measurement data from full bridge Poisson gauges **264**, **266**, **268**, **272**, **274**, and **276**. The computer also has the corresponding locations of the full bridge Poisson gauges relative to the surface of surface modules **254** or **258**. The computer can then calculate the position of applied load and the magnitude of the applied load from the measurement data from the three full bridge Poisson gauges that correspond to the surface module. The measurement data is provided in real-time such that changes in measured force, pressure, or load results in a change in the position of applied load and the load magnitude at the position of applied load. In one embodiment, the position of applied load and the load magnitude is displayed on a display coupled to the computer.

[0081] Referring to FIGS. **2**, **3**, **9**, and **10**, medical sensor **116** is a surface mount device configured to use an automated surface mount technology system to mount medical sensor **116** to a printed circuit board **270**. Medical sensor **116** comprises a substrate **128**. Substrate **128** is configured to flex in a predetermined direction when placed in a medical device. Substrate **128** has a center **160** and a centerline. The centerline goes through center **160** and can be parallel to the X-axis or the Y-axis. A dielectric layer **138** overlies substrate **128**. The dielectric layer **138** can also be a dielectric substrate coupled to substrate **128**. A first strain gauge **120**, a second strain gauge **122**, a third strain gauge **124**, and a fourth strain gauge **126** overlie dielectric layer **138**. Second strain gauge **122** and third strain gauge **124** are configured to measure strain in a predetermined direction. Second strain gauge **122** and third strain gauge **124** are placed symmetrical about center **160** or the centerline of substrate **128**. In one embodiment, a center of second strain gauge **122** and a center of third strain gauge **124** are placed on the centerline. In the example, the center of strain gauge **122** and the center of third strain gauge **124** are placed on the centerline parallel to the Y-axis that couples through the center **160** of substrate **128**.

[0082] Strain gauges **120**, **122**, **124**, and **126** are configured in a full bridge Poisson gauge **144**. In the full bridge Poisson strain gauge **144**, second strain gauge **122** and third strain gauge **124** are active whereby they are used to measure a force, pressure, or load applied to substrate **128**. In one embodiment, the force, pressure, or load is applied to center **160** of substrate **128** or an area of substrate **128** corresponding to center **128**. First strain gauge **120** and fourth strain gauge **126** are non-active in full bridge Poisson strain gauge **144**. In the example, first strain gauge **120** and fourth strain gauge **126** are aligned to measure strain on substrate **128** in the Y-axis direction or perpendicular the active strain gauges. Referring briefly to FIG. **4**, the application of a force,

pressure, or load in medical device **174** as disclosed results in little or no strain to be measured by first strain gauge **120** and fourth strain gauge **126** such that first strain gauge **120** and fourth strain gauge **126** are non-active.

[0083] Interconnect is formed overlying dielectric layer **138**. Similarly, a plurality of pads **130**, **132**, **134**, and **136** are formed overlying dielectric layer **138**. The interconnect and plurality of pads **130**, **132**, **134**, and **136** are formed of a metal such as copper, aluminum, or an alloy. Plurality of pads **130**, **132**, **134**, and **136** are surface mount technology (SMT) pads. The interconnect is configured to couple first strain gauge **120**, second strain gauge **122**, third strain gauge **124**, and fourth strain gauge **126** into full bridge Poisson strain gauge **144**. The interconnect is further configured to couple the full bridge Poisson gauge to plurality of pads **130**, **132**, **134**, and **136**. Plurality of pads **130**, **132**, **134**, and **136** are used in a surface mount technology process to couples full bridge Poisson gauge **144** to a printed circuit board in an automated pick, place, and solder process. In general, the metallization of first strain gauge **120**, second strain gauge **122**, third strain gauge **124**, and fourth strain gauge **126** is of a different metal than the metallization of the interconnect. The strain gauges comprise a measurable resistive material while the interconnect and plurality of pads comprise a low resistance metal.

[0084] In one embodiment, first strain gauge **120**, second strain gauge **122**, third strain gauge **124**, and fourth strain gauge **126** are formed from sputtered metal on dielectric layer **138**. After a sputtered metal layer is deposited overlying dielectric layer **138**, the sputtered metal is patterned, for example using photoresist and etched to remove sputtered metal in predetermined locations to form first strain gauge **120**, second strain gauge **122**, third strain gauge **124**, and fourth strain gauge **126**. In one embodiment, dielectric layer **138** comprises polyamide. Dielectric layer **138** can be deposited overlying substrate **128** or formed in a sheet or substrate that couples to substrate **128**. Typically, substrate **128** comprises a flexible material such as a polymer, metal, or alloy. In one embodiment, substrate **128** comprises 17-7 heat treated stainless steel and is 0.80 millimeters or less in thickness.

[0085] Referring briefly to FIG. **4**, medical device **174** has a support **176** and a support **178** configured to couple respectively to a first end and a second end of substrate **128** of medical sensor **116**. A force, pressure, or load is applied to a structure **170** of medical device **174** is distributed across a predetermined area of substrate **128**. The force, pressure, or load applied to medical sensor **174** is configured to have maximum strain in proximity to the center or centerline of substrate **128** that corresponds to the location of second strain gauge **122** and third strain gauge **124**. Second strain gauge **122** and third strain gauge **124** are configured to measure strain on substrate **128** that can be related to the force, pressure, or load applied to structure **170** of medical device **174**.

[0086] FIG. **11** is a block diagram of electronic circuitry **292** in measurement device **250** in accordance with an example embodiment. In general, electronic circuitry **292** couples to one or more sensors to measure one or more parameters. Components of FIGS. **1**-**5** and **7**-**8** may be referred to in the discussion herein below to relate operation of medical device **250** to electronic circuitry **292**. The sensors can measure parameters such as, height, length, width, tilt/slope, position, orientation, load magnitude, force, pressure, contact point location, displacement, density, viscosity, pH, light, color, sound, optical, vascular flow, visual recognition, humidity, alignment, position, rotation, inertial sensing, turbidity, bone density, fluid viscosity, strain, angular deformity, vibration, torque, elasticity, motion, acceleration, infection, pain, and temperature to name but a few. In the example, electronic circuitry **292** is configured to control a measurement process, receive measurement data from sensors **302**, receive measurement data from position measurement system **342**, and transmit the measurement data to computer **362** for further analysis and feedback. More specifically, sensors **302** measure a force, pressure, or load at predetermined locations of surface module **254** or surface module **258**. Sensors **302** at the predetermined locations underlying surface modules **254** and **258** comprise full bridge Poisson gauges **264**, **266**, **268**, **272**, **274**, and **276** as shown in FIG. **9**. Position measurement system **342** measures position, movement, rotation,

velocity, acceleration, or distance. In one embodiment, position measurement system comprises an inertial measurement unit (IMU) **344** configured to measure 9 degrees of freedom. IMU **344** can comprise one or more inertial sensors. In one embodiment, sensors **302** and position measurement system **342** is housed in medical device **250**. Sensors **302** can comprise other sensors coupled to electronic circuitry **292**.

[0087] Electronic circuitry **292** comprises power management circuitry **300**, control logic **304**, memory **350**, interface circuitry **306**, position measurement system **342**, and wireless communication circuitry **320**. A power source **340** couples to electronic circuitry **292** to power a measurement process. Power source **340** can be an inductor, super capacitor, storage cell, wired power, wireless power, solar cell, energy harvesting device, or other energy storage medium. In one embodiment, power source **340** comprises one or more batteries. Electronic circuitry **292** further includes a transceiver that can be positioned on or within, or engaged with, or attached or affixed to or within, a wide range of physical systems including, but not limited to instruments, equipment, devices, prosthetic components, or other physical systems for use on or in human bodies and configured for sensing and communicating parameters of interest in real time. The components of electronic circuitry **292** are coupled together to form an electronic system using one or more layers of interconnect on printed circuit board **270**. Flexible interconnect can be used to couple electronic circuitry **292** to sensors **302** that are remotely located.

[0088] Electronic circuitry **292** can be configured to provide two-way communication between medical device **250** and computer **362**. In one embodiment, medical device **250** provides quantitative measurement data related to a knee joint installation. Medical device **250** is configured to provide quantitative measurement data related to load magnitude, position of applied load, position, and rotation for the medial or lateral side of the knee in real-time. The measurement data from medical device **250** is used by computer **362** in a kinematic assessment to support installation of prosthetic components to ensure optimal loading, balance, stability, alignment, and range of motion, whereby improved performance and reliability is the result based on clinical evidence.

[0089] Power source **340** provides power to electronic circuitry **292** and sensors **302**. The power source **340** can be temporary or permanent. In one embodiment, the power source is not rechargeable. Medical device **250** is disposable after a single use and the power in the batteries are insufficient for a second surgery. In one embodiment, medical device **250** would be destroyed or disposed of after being used. Alternatively, power source **340** could be rechargeable to support reuse. Medical device **250** would be sterilized before each use. Charging of power source **340** can comprise wired energy transfer or short-distance wireless energy transfer. A charging power source to recharge power source **340** can include, but is not limited to, a battery or batteries, an alternating current power supply, a radio frequency receiver, an electromagnetic induction coil, a photoelectric cell or cells, a thermocouple or thermocouples, or a transducer energy transfer. In one embodiment, energy transfer to power source **340** could be allowed for the single application scenario if power source **340** has insufficient energy to finish the surgery. Furthermore, medical device **250** can utilize power management circuitry **300** to minimize the power drain of power source **340** while in use or when electronic circuitry **292** is idling. A charging operation can be controlled by power management circuitry **300** within electronic circuitry **292**. In one embodiment, power management circuit **300** supports operation of medical device **250** during charging thereby allowing the surgery to continue if a low charge on power source **340** is detected. For example, power can be transferred to the batteries, capacitive energy storage device, or inductive energy storage device by way of efficient step-up and step-down voltage conversion circuitry. This conserves operating power of circuit blocks at a minimum voltage level to support the required level of performance.

[0090] Power management circuitry **300** is configured to operate under severe power constraints. In one embodiment, power management circuitry **300** controls power up, power down, and minimizes power usage during operation. The power management circuitry **300** is configured to reduce power dissipation during operation of the system. The power management circuitry **300** can turn off or

reduce the power delivered to circuits that are not being used in a specific operation. Similarly, if the system is idle and not being used, the power management circuitry **300** can put other unused circuitry in a sleep mode that awakens prior to the next measurement being made. Power management circuitry **300** can include one or more voltage regulation circuits that provide a plurality of different stable voltages to electronic circuitry **292** and sensors **302**.

[0091] In one configuration, a charging operation of power source **340** can further serve to communicate downlink data to electronic circuitry. For instance, downlink control data can be modulated onto the energy source signal and thereafter demodulated from an inductor in electronic circuitry **230**. This can serve as a more efficient way for receiving downlink data instead of configuring an internal transceiver within electronic circuitry **230** for both uplink and downlink operation. As one example, downlink data can include updated control parameters that medical device **250** uses when making a measurement, such as external positional information or for recalibration purposes. It can also be used to download a serial number or other identification data.

[0092] Control logic **304** controls a measurement process or sequence that engages sensors **302**, converts the measurement data into a useable format, and transmits the measurement information. Control logic **304** can comprise digital circuitry, a microcontroller, a microprocessor, an ASIC (Application Specific Integrated Circuit), a DSP (Digital Signal Processing), a gate array implementation, a standard cell implementation, and other circuitry. Control logic **304** is configured to store measurement data, software routines, diagnostics/test routines, calibration data, calibration algorithms, workflows, and other information or programs in memory **350** In one embodiment, measurement data from one or more sensors may be continuously enabled and sampled periodically to memory **350**. Control logic **304** couples to memory **350** and is configured to store and retrieve information from memory **350**. Control logic **304** controls the measurement process, stores the measurement data in memory **350**, or transmits the measurement data in real-time. Control logic **304** can include dedicated ports that couple to a sensor to continuously receive measurement data or receive updated measurements at high sample rates. Alternatively, control logic **304** can select a sensor to be measured. For example, multiple sensors can be coupled to control logic **304** via a multiplexer. Control logic **304** controls which sensor is coupled through the multiplexer to sample and output the measurement data. Multiplexed measurement data works well when the measurement data is not critical or can be sampled occasionally as needed. Control logic **304** can also select and receive measurement data from different sensors in a sequence or simultaneously through parallel channels. Control logic **304** can be configured to monitor the measurement data from a sensor but transmit measurement data only when a change occurs in the measurement data. Furthermore, control logic **304** can modify the measurement data prior to transmitting the measurement data to computer **362**. For example, the measurement data can be corrected for non-linearity of the sensor using calibration data stored in memory. In one embodiment, a microcontroller with Bluetooth low energy (BLE) is used with an analog to digital converter to convert analog values to digital.

[0093] Interface circuitry **306** couples between sensors **302** and control logic **304**. Interface circuitry **306** supports conversion of a sensor output to a form that can be received by computer **362**. Interface circuitry **306** comprises digital circuitry and analog circuitry. The analog circuitry can include multiplexers, amplifiers, buffers, comparators, filters, passive components, analog to digital converters, and digital to analog converters to name but a few. In one embodiment interface circuitry **306** uses one or more multiplexers to select a sensor for providing measurement data to control logic **304**, memory **350**, or wireless communication circuitry **320**. Control logic **304** is configured to provide control signals that enable the multiplexer to select the sensor for measurement. Typically, at least one analog to digital conversion or digital to analog conversion of the measurement data occurs via the interface circuitry **306**.

[0094] Sensors **302** couple through interface circuitry **306** to memory **350**. Alternatively, interface circuitry **306** can couple directly to circuitry for transmitting measurement data as it is measured.

The physical parameter or parameters of interest measured by sensors **302** are force, pressure, or load as disclosed herein but sensors **302** can further include other sensors that measure height, length, width, tilt/slope, position, orientation, load magnitude, force, pressure, contact point location, displacement, density, viscosity, pH, light, color, sound, optical, vascular flow, visual recognition, humidity, alignment, rotation, inertial sensing, turbidity, bone density, fluid viscosity, strain, angular deformity, vibration, torque, elasticity, motion, and temperature. Often, a measured parameter is used in conjunction with another measured parameter to make a kinetic and qualitative assessment. In joint reconstruction, portions of the musculoskeletal system are prepared to receive prosthetic components. Preparation includes bone cuts or bone shaping to mate with one or more prosthesis. Parameters can be evaluated relative to orientation, stability, alignment, impingement, direction, displacement, or position as well as movement, rotation, or acceleration along an axis or combination of axes by wireless sensing modules or devices positioned on or within a body, instrument, appliance, vehicle, equipment, or other physical system.

[0095] Sensors **302** can directly or indirectly measure a parameter of interest. For example, a load sensor in medical device **250** can comprise a strain gauge, a full bridge Poisson gauge, a capacitor, a piezo-sensor, or a MEMs sensor. Measuring load with a full bridge Poisson gauge is an indirect form of sensing as the strain measurement of the full bridge Poisson gauge will change with the amount of loading applied to a substrate of the load sensor. The resistive or voltage measurement data from the full bridge Poisson gauge can be sent to computer **362** for further processing. In one embodiment, computer **362** can include software and calibration data related to the full bridge Poisson gauge. Alternatively, the calibration data can be stored with electronic circuitry **292** which is then downloaded to computer **363** prior to a measurement. The load measurement data can be converted from the strain measurements to load measurements. Computer **362** can store calibration data that can be used to curve fit and compensate for non-linear output of a sensor over a range of operation. Furthermore, the individual sensor measurement can be combined to produce other measurement data by computer **362**. In keeping with the example of load measurement data, the individual load measurement data can be combined or assessed to determine a location where the load is applied to a surface to which the load sensors couple. The measurement data can be displayed on a display that supports a surgeon rapidly assimilating the measurement data. For example, the calculated measurement data on the location of applied load to a surface may have little or no meaning to a surgeon. Conversely, an image of the surface being loaded with a contact point displayed on the surface can be rapidly assimilated by the surgeon to determine if there is an issue with the contact point.

[0096] In one embodiment, the knee joint system transmits and receives information wirelessly. Wireless operation reduces clutter within the surgical area, wired distortion of, or limitations on, measurements caused by the potential for physical interference by, or limitations imposed by, cables connecting a device with an internal power with data collection, storage, or display equipment in an operating room environment. Electronic circuitry **292** includes wireless communication circuitry **320**. In one embodiment, wireless communication circuitry **320** is configured for short range telemetry and battery operation. Typically, medical device **250**, and computer **362** are located in an operating room such that the transmission of measurement to computer **362** is less than 10 meters. As illustrated, the exemplary communications system comprises wireless communication circuitry **320** of medical device **250** and receiving system wireless communication circuitry **322** of computer **362**. Wireless communications circuitry **320** comprises, but is not limited to, the antenna **360**, a matching network **316**, the telemetry transceiver **314**, a CRC circuit **312**, a data packetizer **310**, and a data input **308**. Wireless communication circuitry **320** can include more or less than the number of components shown and are not limited to those shown or the order of the components.

[0097] Similarly, computer **362** includes wireless communication circuitry **322**. Wireless communication circuitry **322** comprises an antenna **324**, a matching network **326**, a telemetry

transceiver **328**, a CRC circuit **330**, and a data packetizer **332**. Notably, other interface systems can be directly coupled to the data packetizer **332** for processing and rendering sensor data. In general, electronic circuitry **292** couples to sensors **302** and is configured to transmit quantitative measurement data to computer **362** in real-time to process, display, analyze, and provide feedback. Medical device **250** includes a plurality of full bridge Poisson gauges configured to measure loads applied to surface module **254** or surface module **258**. Medical device **250** further includes an inertial measurement unit comprising one or more inertial sensors and other parameter measurement sensors as listed herein above. The measurement data from the plurality of load sensors and the inertial sensors is transmitted to computer **362**. Computer **362** can calculate a load magnitude applied to surface module **254** or surface module **258** from the plurality of load sensors. In the example, three load sensors at predetermined positions are used to measure a position of applied load and a load magnitude at the position of applied load. In one embodiment, computer **362** calculates a position of applied load (contact point) to surface module **254** or surface module **258** of medical device **250**. Medical device **250** can further use measurement data from position measurement system **342** to monitor position and movement of medical device **250** or the musculoskeletal system. The position or tracking data from position measurement system **342** is also sent to computer **362**. The results can also be displayed on display **364** of computer **362**. In one embodiment, measurement data from position measurement system **342** can be used to measure range of motion, alignment, and impingement. In one embodiment, the transmission of the measurement data from different sensors or components can be sent on different channels or the measurement data can be sent at different times on the same channel.

[0098] As mentioned previously, wireless communication circuitry comprises data input **308**, data packetizer **310**, CRC circuit **312** telemetry transmitter **314**, matching network **316**, and antenna **360**. In general, measurement data from sensors **302** is provided to data input **308** of wireless communication circuitry **320**. In one embodiment, the measurement data from sensors **302** can come directly from interface circuitry **306**, from memory **350** or from a combination of paths to data input **308**. In one embodiment, measurement data can be stored in memory **350** prior to being provided to data input **308**. Data packetizer **310** assembles the measurement data into packets and includes sensor information received or processed by memory **350**. Memory **350** can comprise specific modules for efficiently performing core signal processing functions of the medical device **250**. Memory **350** provides the further benefit of reducing the form factor to meet dimensional requirements for integration into medical device **250**.

[0099] In general, measurement data from medical device **250** is encrypted. In one embodiment, the output of data packetizer **310** couples to the input of CRC circuit **312**. CRC circuit **312** applies error code detection on the packet data. The cyclic redundancy check is based on an algorithm that computes a checksum for a data stream or packet of any length. These checksums can be used to detect interference or accidental alteration of data during transmission. Cyclic redundancy checks are especially good at detecting errors caused by electrical noise and therefore enable robust protection against improper processing of corrupted data in environments having high levels of electromagnetic activity. The output of CRC circuit **312** couples to the input of telemetry transceiver **314**. The telemetry transceiver **314** then transmits the CRC encoded data packet through the matching network **316** by way of the antenna **360**. Telemetry transceiver **314** can increase a carrier frequency in one or more steps and add the information or measurement data from medical device **250** to the carrier frequency. The matching network **316** provides an impedance match for achieving optimal communication power efficiency between telemetry transceiver **314** and antenna **360**.

[0100] Antenna **360** can be integrated with components of the medical device **250** to provide the radio frequency transmission. The substrate for the antenna **360** and electrical connections with the electronic circuitry **292** can further include the matching network **316**. In one embodiment, the antenna **360** and a portion of the matching network **316** can be a wire or formed in printed circuit

board **270** that interconnects the components that comprise electronic circuitry **292**. This level of integration of the antenna and electronics enables reductions in the size and cost of wireless equipment. Potential applications may include, but are not limited to any type musculoskeletal equipment or prosthetic components where a compact antenna can be used. This includes disposable modules or devices as well as reusable modules or devices and modules or devices for long-term use.

[0101] The process for receiving wireless communication circuitry **322** is the opposite of the sending process. Antenna **324** receives transmitted measurement data from wireless communication circuitry **320** Wireless communication circuitry **320** can transmit at low power such that receiving wireless communication circuitry **322** must be in proximity, for example within **10** meters to receive measurement data. Antenna **324** couples to matching network **326** that efficiently couples the measurement data to telemetry transceiver **328**. The measurement data can be sent on a carrier signal that supports wireless transmission. The measurement data is stripped off from the carrier signal by telemetry transceiver **328**. The measurement data is received by CRC circuit **330** from telemetry transceiver **328**. CRC circuit **330** performs a cyclic redundancy check algorithm to verify that the measurement data has not been corrupted during transmission. The CRC circuit **330** provides the checked measurement data to data packetizer **332**. Data packetizer **332** reassembles the measurement data where it is provided to USB interface **334**. USB interface **334** provides the measurement data to computer **362** for further processing.

[0102] It should be noted that the measuring, transmitting, receiving, and processing of the measurement data can be performed in real-time for use by a surgeon to support installation of a prosthetic joint. In one embodiment, computer **362** displays at least a portion of medical device **250**. In the example, surface module **254** or surface module **258** of medical device **250** is displayed on display **364** coupled to computer **362**. Measurement data from sensors **302** and position measurement system **342** is used to calculate a load magnitude and a position of applied load on surface module **254** or surface module **258** of medical device **250**. The location of each full bridge Poisson gauge is known relative to surface module **254** or surface module **258**. The position of applied load can be calculated using the location information from each load sensor and the load magnitude at each location by computer **362** as disclosed in detail herein above. The position of applied load is also called contact point **382** on GUI **380** of display **364**. Similarly, the load magnitude at contact point **382** can be calculated from three or more full bridge Poisson gauges and the locations of the three or more full bridge Poisson gauges relative to a surface of the surface module of medical device **250**. In one embodiment, the minimum load, the maximum load, and the load at the current location are displayed on GUI **380** respectively in display boxes **380**, **390**, and **386**. The amount of rotation or range of motion can also be indicated. These measurements are measured or calculated in real-time and displayed on display **364**. Adjustments can be performed that affect alignment, loading, position of load, rotation, or other parameters and monitored in real-time on display **364**. The adjustments can support optimization after the measured parameters are within specification to fine tune the prosthetic component installation with quantitative measurement data.

[0103] In general, a surgeon moves the knee joint through a range of motion to generate measurement data in a trialing of the knee joint. The measurement data from sensors **302** in medical device **150** is transmitted to computer **362**. Computer **362** processes the information and displays the information in a manner where quantitative measurement data can be rapidly assimilated by the surgeon or surgical team. The measurement data can be displayed or it can be presented graphically or audibly. A picture of a portion of medical device **250** is displayed on display **364**. In the example, a surface **384** is displayed on display **364** that corresponds to a surface of surface module **254** or surface module **258**. In one embodiment, measurement data from sensors **302** at predetermined locations are used to determine contact point **382** on display **364**. Display **364** can further add measurement data or graphics to disclose movement of contact point **384** on surface

384. In one embodiment, movement of contact point **384** will be non-linear. In one embodiment, display **364** may display a three dimensional type of animation to illustrate to a surgeon or surgical team a location of contact point **382** on surface **384**. This allows the surgeon to understand loading or location of the loading at different leg positions over the range of motion. Alternatively, more than one view or different orientations of surface **384** can be provided on display **364** to better illustrate a location of contact point **382** on surface **384**. A display box **386** discloses the load magnitude in real-time on GUI **380** as the knee joint is moved through the range of motion. In one embodiment, computer **362** or medical device **250** can include software having a force location and load magnitude algorithm that calculates contact point **382** and load magnitude as displayed in display box **386** from the measurement data received from medical device **250**. In the example, the measurement data comprises information from three full bridge Poisson gauges measuring loading applied to the surface of surface module **254** or three full bridge Poisson gauges measuring loading applied to the surface of surface module **258**. A reference sensor can also be incorporated in medical device **250** to support measurement accuracy.

[0104] Position measurement system **342** is configured to measure position or motion. In one embodiment, position measurement system **342** is configured to be housed in medical device **250**. In one embodiment, position measurement system **342** is an inertial measurement unit (IMU). Computer **362** or medical device **250** can further have quaternion and range of motion algorithms to support measurement of movement and position. Calibration information can be accessed for the IMU or load sensors and used with the force location, load magnitude, and impingement measurements. In one embodiment, calibration information or calibration data corresponds to test measurements on medical device **250**. In one embodiment, the calibration data can be stored on non-volatile memory such as EEPROM within medical device **250**. As the knee joint is moved through a predetermined range of motion there will be a minimum load magnitude measured at a first location and a maximum load magnitude measured at a second location on surface **384** for a predetermined range of motion. The minimum load magnitude is indicated in display box **388** on GUI **380** that is continuously updated should a lower value occur. Similarly, the maximum load magnitude is indicated in display box **390** on GUI **380** that is continuously updated. In one embodiment, force vector data can be used to detect impingement. GUI **380** will notify the surgeon or surgical team when impingement is detected by audible, visual, or haptic means. In one embodiment, the IMU comprises one or more inertial sensors and is housed in medical device **250**. The IMU can track position, motion, and can also be used in conjunction with the force vector data or alone to determine impingement. Impingement may not occur in a knee joint but can occur in other joints that are measured such as a shoulder joint or hip joint.

[0105] In the example, an exit button **492**, a LOG button **494**, a zero button **496**, a reset button **392**, and a ROM button **470** are provided on GUI **380**. In one embodiment, exit button **492** toggles between coupling medical device **250** and decoupling medical device **250** from computer **362**. In one embodiment, exit button **492** will indicate when medical device **250** is coupled to computer **362**. In one embodiment, enabling LOG button **494** logs data for 10 seconds. In one embodiment, enabling zero button **496** zeroes load data offsets. In one embodiment, enabling reset button **392** resets display box **388** and display box **390** to the current load magnitude value. In one embodiment, enabling ROM button **370** initiates a range of motion test. ROM button **370** further initializes the IMU for the range of motion test. Battery indicator **426** indicates an amount of power left in the power source. In the example, the power source comprises one or more batteries. In one embodiment, battery indicator **426** indicates the percentage of power remaining in the one or more batteries of medical device **250**. In one embodiment, indicator **426** can provide an estimation of an operating time of medical device **250** based on the average current drain from the batteries. GUI **380** further includes a tracking function that displays dynamic motion of contact point **382** through the full range of motion to evaluate joint kinetics. GUI **380** can also indicate or leave a location trace where loading exceeds a predetermined threshold.

[0106] Medical device **250** coupling to computer **362** is indicated on GUI **380**. An indicator on GUI **380** shows the signal strength of the wireless connection to medical device **250**. A signal strength is displayed on an indicator on display **364** that provides an indication of the connection and ability to transfer measurement data to computer **362**. In one embodiment, the wireless connection is a Bluetooth low energy connection that opens a connection dialog between computer **362** and any Bluetooth devices. Computer **362** is used to select medical device **250** for connection and initiates the wireless connection. In one embodiment, calibration data and device information from medical device **250** is downloaded to computer **362**. Medical device **250** couples to computer **362** and begins to stream measurement data. In one embodiment, GUI **380** zeroes any load data and then begins showing a measured load magnitude at contact point **382** in display box **386**.

[0107] Impingement occurs when a prosthetic joint impinges on bone or soft tissue. Impingement may also occur in the soft tissue around a prosthetic joint. Soft tissue impingement is often called acromial impingement. Impingement information can be displayed on GUI **380**. In one embodiment, a rim of the surface on display **364** is used to show if impingement occurs and approximately where the impingement occurs. A portion of the rim will be highlighted by a color change or a gray scale change on the portion of the rim in proximity to where the impingement occurs. In one embodiment, the portion of the rim in proximity to the impingement will turn red when impingement is detected.

[0108] FIG. **12** is a block diagram of a system or a computer in accordance with an example embodiment. The exemplary diagrammatic representation of a machine, device, system, or computer in the form of a system within which a set of instructions, when executed, may cause the machine to perform any one or more of the methodologies discussed above. In some embodiments, the machine operates as a standalone device. In some embodiments, the machine may be connected (e.g., using a network) to other machines. In a networked deployment, the machine may operate in the capacity of a server or a client user machine in server-client user network environment, or as a peer machine in a peer-to-peer (or distributed) network environment.

[0109] The machine may comprise a server computer, a client user computer, a personal computer (PC), a tablet PC, a laptop computer, a desktop computer, a control system, logic circuitry, a sensor system, an ASIC, an integrated circuit, a network router, switch or bridge, or any machine capable of executing a set of instructions (sequential or otherwise) that specify actions to be taken by that machine. It will be understood that a device of the present disclosure includes broadly any electronic device that provides voice, video or data communication. Further, while a single machine is illustrated, the term "machine" shall also be taken to include any collection of machines that individually or jointly execute a set (or multiple sets) of instructions to perform any one or more of the methodologies discussed herein.

[0110] The system may include a processor **402** (e.g., a central processing unit (CPU), a graphics processing unit (GPU, or both), a main memory **404** and a static memory **406**, which communicate with each other via a bus **408**. The system may further include a video display unit **410** (e.g., a liquid crystal display (LCD), a flat panel display, a solid state display, or a cathode ray tube display (CRT)). The system may include an input device **412** (e.g., a keyboard), a cursor control device **414** (e.g., a mouse), a disk drive unit **416**, a signal generation device **418** (e.g., a speaker or remote control) and a network interface device **420**.

[0111] The drive unit **416** can be other types of memory such as flash memory and may include a machine-readable medium **422** on which is stored one or more sets of instructions **424** (e.g., software) embodying any one or more of the methodologies or functions described herein, including those methods illustrated above. Instructions **424** may also reside, completely or at least partially, within the main memory **404**, the static memory **406**, and/or within the processor **402** during execution thereof by the system. Main memory **404** and the processor **402** also may constitute machine-readable media.

[0112] Dedicated hardware implementations including, but not limited to, application specific

integrated circuits, programmable logic arrays and other hardware devices can likewise be constructed to implement the methods described herein. Applications that may include the apparatus and systems of various embodiments broadly include a variety of electronic and computer systems. Some embodiments implement functions in two or more specific interconnected hardware modules or devices with related control and data signals communicated between and through the modules, or as portions of an application-specific integrated circuit. Thus, the example system is applicable to software, firmware, and hardware implementations.

[0113] In accordance with various embodiments of the present disclosure, the methods described herein are intended for operation as software programs running on a computer processor. Furthermore, software implementations can include, but not limited to, distributed processing or component/object distributed processing, parallel processing, or virtual machine processing can also be constructed to implement the methods described herein.

[0114] The present disclosure contemplates a machine readable medium containing instructions **424**, or that which receives and executes instructions **424** from a propagated signal so that a device connected to a network environment **420** can send or receive voice, video or data, and to communicate over the network **426** using the instructions **424**. The instructions **424** may further be transmitted or received over the network **426** via the network interface device **420**.

[0115] While the machine-readable medium **422** is shown in an example embodiment to be a single medium, the term "machine-readable medium" should be taken to include a single medium or multiple media (e.g., a centralized or distributed database, and/or associated caches and servers) that store the one or more sets of instructions. The term "machine-readable medium" shall also be taken to include any medium that is capable of storing, encoding or carrying a set of instructions for execution by the machine and that cause the machine to perform any one or more of the methodologies of the present disclosure.

[0116] The term "machine-readable medium" shall accordingly be taken to include, but not be limited to: solid-state memories such as a memory card or other package that houses one or more read-only (non-volatile) memories, random access memories, or other re-writable (volatile) memories; magneto-optical or optical medium such as a disk or tape; and carrier wave signals such as a signal embodying computer instructions in a transmission medium; and/or a digital file attachment to e-mail or other self-contained information archive or set of archives is considered a distribution medium equivalent to a tangible storage medium. Accordingly, the disclosure is considered to include any one or more of a machine-readable medium or a distribution medium, as listed herein and including art-recognized equivalents and successor media, in which the software implementations herein are stored.

[0117] Although the present specification describes components and functions implemented in the embodiments with reference to particular standards and protocols, the disclosure is not limited to such standards and protocols. Each of the standards for Internet and other packet switched network transmission (e.g., TCP/IP, UDP/IP, HTML, HTTP) represent examples of the state of the art. Such standards are periodically superseded by faster or more efficient equivalents having essentially the same functions. Accordingly, replacement standards and protocols having the same functions are considered equivalents.

[0118] FIG. **13** is an illustration of a communication network **500** for measurement and reporting in accordance with an exemplary embodiment. Briefly, the communication network **500** expands broad data connectivity to other devices or services. As illustrated, the measurement system **502** can be communicatively coupled to the communications network **500** and any associated systems or services.

[0119] As one example, measurement system **502** can share its parameters of interest (e.g., angles, load, balance, distance, alignment, displacement, movement, rotation, and acceleration) with remote services or providers, for instance, to analyze or report on surgical status or outcome. This data can be shared for example with a service provider to monitor progress or with plan

administrators for surgical monitoring purposes or efficacy studies. The communication network **500** can further be tied to an Electronic Medical Records (EMR) system to implement health information technology practices. In other embodiments, the communication network **500** can be communicatively coupled to HIS Hospital Information System, HIT Hospital Information Technology and HIM Hospital Information Management, EHR Electronic Health Record, CPOE Computerized Physician Order Entry, and CDSS Computerized Decision Support Systems. This provides the ability of different information technology systems and software applications to communicate, to exchange data accurately, effectively, and consistently, and to use the exchanged data.

[0120] The communications network **500** can provide wired or wireless connectivity over a Local Area Network (LAN) **504**, a Wireless Local Area Network (WLAN) **510**, a Cellular Network **506**, and/or other radio frequency (RF) system. The LAN **504** and WLAN **510** can be communicatively coupled to the Internet **508**, for example, through a central office. The central office can house common network switching equipment for distributing telecommunication services. Telecommunication services can include traditional POTS (Plain Old Telephone Service) and broadband services such as cable, HDTV, DSL, VoIP (Voice over Internet Protocol), IPTV (Internet Protocol Television), Internet services, and so on.

[0121] The communication network **500** can utilize common computing and communications technologies to support circuit-switched and/or packet-switched communications. Each of the standards for Internet **508** and other packet switched network transmission (e.g., TCP/IP, UDP/IP, HTML, HTTP, RTP, MMS, or SMS) represent examples of the state of the art. Such standards are periodically superseded by faster or more efficient equivalents having essentially the same functions. Accordingly, replacement standards and protocols having the same functions are considered equivalent.

[0122] The cellular network **506** can support voice and data services over a number of access technologies such as GSM-GPRS, EDGE, CDMA, UMTS, WiMAX, 2G, 3G, 4G, 5G, WAP, software defined radio (SDR), and other known technologies. The cellular network **506** can be coupled to base receiver **512** under a frequency-reuse plan for communicating with mobile devices **514**.

[0123] The base receiver **512**, in turn, can connect the mobile device **514** to the Internet **508** over a packet switched link. The internet **508** can support application services and service layers for distributing data from the measurement system **502** to the mobile device **514**. Mobile device **514** can also connect to other communication devices through the Internet **508** using a wireless communication channel. The mobile device **514** can also connect to the Internet **508** over the WLAN **510**. Wireless Local Access Networks (WLANs) provide wireless access within a local geographical area. WLANs are typically composed of a cluster of Access Points (APs) **516** also known as base stations. The measurement system **502** can communicate with other WLAN stations such as laptop **518** within the base station area. In typical WLAN implementations, the physical layer uses a variety of technologies such as 802.11b, 802.11g, 802.11n, 802.11ac, or WLAN technologies. The physical layer may use infrared, frequency hopping spread spectrum in the 2.4 GHz Band, direct sequence spread spectrum in the 2.4 GHz Band, or other access technologies, for example, in the 5.8 GHz ISM band or higher ISM bands (e.g., 24 GHz, etcetera).

[0124] By way of the communication network **500**, the measurement system **502** can establish connections with a remote server **520** on the network and with other mobile devices for exchanging data. The remote server **520** can have access to a database **522** that is stored locally or remotely and which can contain application specific data. The remote server **420** can also host application services directly, or over the internet **508**.

[0125] While the present invention has been described with reference to particular embodiments, those skilled in the art will recognize that many changes may be made thereto without departing from the spirit and scope of the present invention. Each of these embodiments and obvious

variations thereof is contemplated as falling within the spirit and scope of the claimed invention, which is set forth in the claims. While the subject matter of the invention is described with specific examples of embodiments, the foregoing drawings and descriptions thereof depict only typical embodiments of the subject matter and are not therefore to be considered to be limiting of its scope, it is evident that many alternatives and variations will be apparent to those skilled in the art. Thus, the description of the invention is merely descriptive in nature and, thus, variations that do not depart from the gist of the invention are intended to be within the scope of the embodiments of the present invention. Such variations are not to be regarded as a departure from the spirit and scope of the present invention.

[0126] While the present invention has been described with reference to embodiments, it is to be understood that the invention is not limited to the disclosed embodiments. The scope of the following claims is to be accorded the broadest interpretation so as to encompass all modifications, equivalent structures and functions. For example, if words such as "orthogonal", "perpendicular" are used the intended meaning is "substantially orthogonal" and "substantially perpendicular" respectively. Additionally although specific numbers may be quoted in the claims, it is intended that a number close to the one stated is also within the intended scope, i.e. any stated number (e.g., 90 degrees) should be interpreted to be "about" the value of the stated number (e.g., about 90 degrees).

[0127] As the claims hereinafter reflect, inventive aspects may lie in less than all features of a single foregoing disclosed embodiment. Thus, the hereinafter expressed claims are hereby expressly incorporated into this Detailed Description of the Drawings, with each claim standing on its own as a separate embodiment of an invention. Furthermore, while some embodiments described herein include some but not other features included in other embodiments, combinations of features of different embodiments are meant to be within the scope of the invention, and form different embodiments, as would be understood by those skilled in the art. [0128] **1-20**. (canceled)

Claims

21. A device, comprising: a sensor array configured to measure deformation along a first direction, wherein the sensor array includes a first strain gauge, a second strain gauge, a third strain gauge opposite the second strain gauge about a first line parallel to the first direction, and a fourth strain gauge opposite the first strain gauge about a second line parallel to a second direction perpendicular to the first direction, wherein the device is configured to produce a region of maximum strain encompassing the second line in response to a force causing deformation along the first direction, wherein the second strain gauge and the third strain gauge are configured to be active when the force causes deformation along the first direction, and wherein the first strain gauge and the fourth strain gauge are configured to be inactive when the force causes deformation along the first direction.

22. The device of claim 21, wherein the device is configured to produce the region of maximum strain by allowing deformation along the first direction and preventing deformation along the second direction.

23. The device of claim 21, wherein the second strain gauge and the third strain gauge are positioned along the second line.

24. The device of claim 23, wherein the second strain gauge and the third strain gauge are spaced apart from the first line by a first distance and wherein the first strain gauge and the fourth strain gauge are spaced apart from the second line by a second distance that is greater than the first distance.

25. The device of claim 24, wherein the second distance is at least one half of a length of the second and third strain gauges.

26. The device of claim 21, wherein the second strain gauge and the third strain gauge are centered

about the second line.

27. The device of claim 21, wherein the first strain gauge and the fourth strain gauge are positioned outside of the region of maximum strain.

28. The device of claim 23, wherein the first strain gauge and the fourth strain gauge are centered about the first line.

29. The device of claim 21, wherein the first strain gauge, the second strain gauge, the third strain gauge, and the fourth strain gauge form a full bridge Poisson gauge.

30. The device of claim 21, wherein the device is included in a prosthetic component.

31. A device, comprising: a sensor array configured to measure deformation along a first direction, wherein the device includes a center point, wherein the device is configured to allow deformation along the first direction and to prevent deformation along a second direction perpendicular to the first direction, wherein the sensor array includes a first strain gauge, a second strain gauge, a third strain gauge opposite the second strain gauge about a first line passing through the center point and parallel to the first direction, and a fourth strain gauge opposite the first strain gauge about a second line passing through the center point and parallel to the second direction, wherein the second strain gauge and the third strain gauge are configured to measure strain in the first direction, wherein the first strain gauge and the fourth strain gauge are configured to measure strain in the second direction, wherein the second strain gauge and the third strain gauge are configured to be active when a force causes the substrate to deform along the first direction, and wherein the first strain gauge and the fourth strain gauge are configured to be inactive when the force causes the substrate to deform along the first direction.

32. The device of claim 31, wherein the second strain gauge and the third strain gauge are spaced apart from the center point by a first distance, and wherein the first strain gauge and the fourth strain gauge are spaced apart from the center point by a second distance that is greater than the first distance.

33. The device of claim 32, wherein the second distance is at least one half of a length of the second and third strain gauges.

34. The device of claim 31, wherein the second strain gauge and the third strain gauge are positioned along the second line.

35. The device of claim 31, wherein the device is included in a prosthetic component.

36. A device, comprising: a sensor array configured to measure deformation along a first direction, wherein the sensor array includes a first strain gauge, a second strain gauge, a third strain gauge opposite the second strain gauge about a first line parallel to the first direction, and a fourth strain gauge opposite the first strain gauge about a second line parallel to a second direction perpendicular to the first direction, wherein the second strain gauge and the third strain gauge are configured to be active when a force causes deformation along the first direction, and wherein the first strain gauge and the fourth strain gauge are configured to be inactive when the force causes deformation along the first direction; and electronic circuitry configured to receive measurement data from the sensor array and transmit the measurement data to a computing device external to the device.

37. The device of claim 36, wherein the measurement data includes resistance measurements or voltage measurements.

38. The device of claim 36, further comprising a power source and wherein the electronic circuity includes power management circuitry configured to minimize power drain of the power source.

39. The device of claim 36, wherein the first strain gauge, the second strain gauge, the third strain gauge, and the fourth strain gauge form a full bridge Poisson gauge.

40. The device of claim 36, wherein the device is included in a prosthetic component.