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(12) **United States Patent**
Zand et al.

(10) **Patent No.: US 9,204,830 B2**
(45) **Date of Patent: Dec. 8, 2015**

(54) **SURGICAL INSTRUMENTS WITH SENSORS FOR DETECTING TISSUE PROPERTIES, AND SYSTEM USING SUCH INSTRUMENTS**

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(73) Assignee: **SURGISENSE CORPORATION**, Bethesda, MD (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1821 days.

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(86) PCT No.: **PCT/US2006/013985**

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(2), (4) Date: **Oct. 15, 2007**

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PCT Pub. Date: **Oct. 26, 2006**

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Related U.S. Application Data

(60) Provisional application No. 60/671,872, filed on Apr. 15, 2005, provisional application No. 60/766,359, filed on Jan. 12, 2006.

(51) **Int. Cl.**
A61B 5/1455 (2006.01)
A61B 5/145 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 5/14542*** (2013.01); ***A61B 5/0071*** (2013.01); ***A61B 5/0086*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC .. A61B 5/6837; A61B 5/0071; A61B 5/0086; A61B 5/14542; A61B 5/0261; A61B 5/0075; A61B 5/0084; A61B 5/413; A61B 17/04; A61B 17/0401; A61B 2017/00022
USPC 600/300, 310, 323, 317, 361, 407, 504, 600/549, 554; 606/139, 151, 32, 167, 205, 606/191, 210, 222; 604/19
See application file for complete search history.

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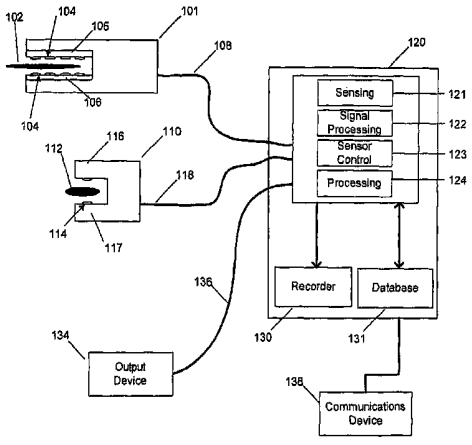
Primary Examiner — Eric Winakur
(74) *Attorney, Agent, or Firm* — McDermott Will & Emery LLP

(57) **ABSTRACT**

A system is provided that furnishes expert procedural guidance based upon patient-specific data gained from surgical instruments incorporating sensors on the instrument's working surface, one or more reference sensors placed about the patient, sensors implanted before, during or after the procedure, the patient's personal medical history, and patient status monitoring equipment. Embodiments include a system having a surgical instrument with a sensor for generating a signal indicative of a property of a subject tissue of the patient, which signal is converted into a current dataset and stored. A processor compares the current dataset with other previously stored datasets, and uses the comparison to assess a physical condition of the subject tissue and/or to guide a procedure being performed on the tissue.

83 Claims, 22 Drawing Sheets



(51) **Int. Cl.**

A61B 5/00	(2006.01)
A61B 5/026	(2006.01)
A61B 5/1459	(2006.01)
A61B 17/00	(2006.01)

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

CPC ***A61B5/0261*** (2013.01); ***A61B 5/1459*** (2013.01); ***A61B 5/6837*** (2013.01); *A61B 5/0075* (2013.01); *A61B 5/0084* (2013.01); *A61B 5/413* (2013.01); *A61B 2017/00022* (2013.01)

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Company Description: Technologies and Intellectual Property: SPY Imaging Technology, available in novadaq.com. Retrieved on Apr. 24, 2015 at http://novadaq.com/company/technologies-ip.

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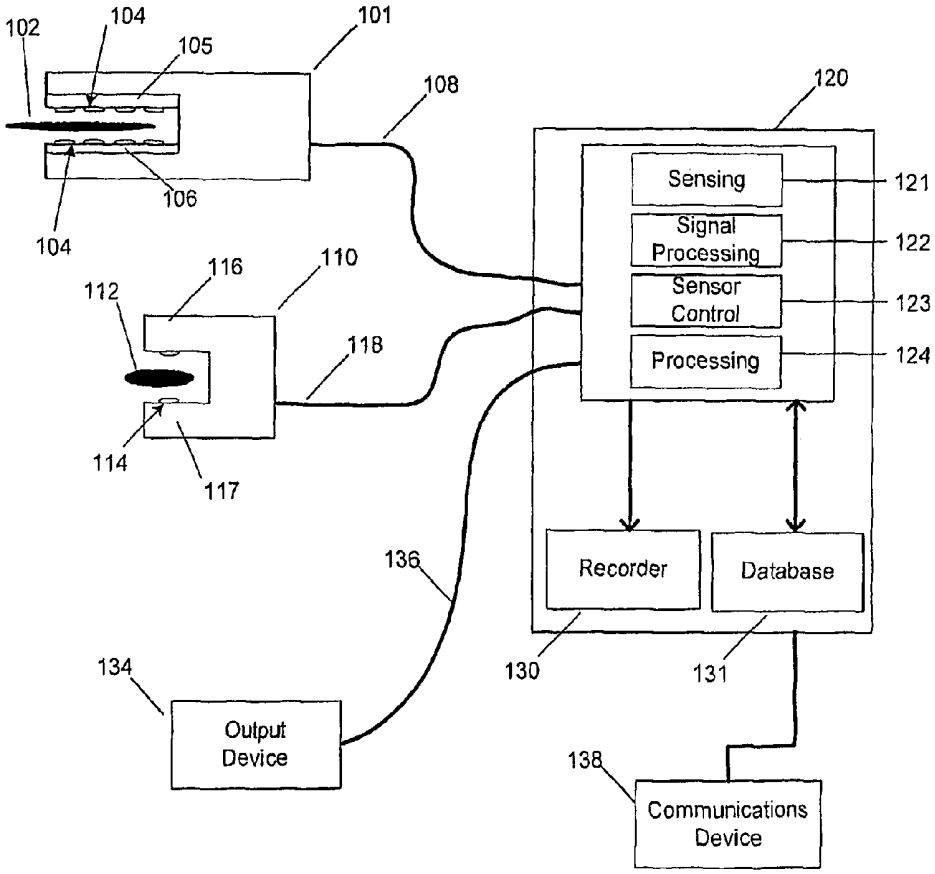
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104
105
101
108
120
106
104
Sensing
121
Signal Processing
122
Sensor Control
123
Processing
124
116
110
112
118
114
117
136
Recorder
Database
130
131
134
Output Device
138
Communications Device

Figure 1

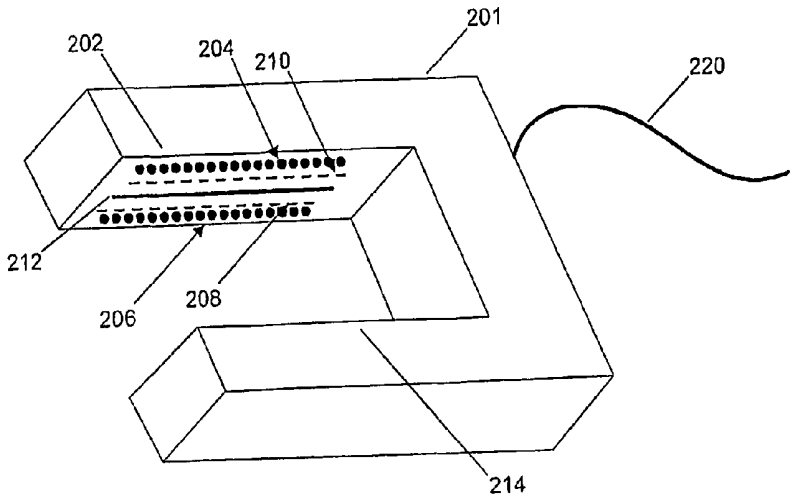
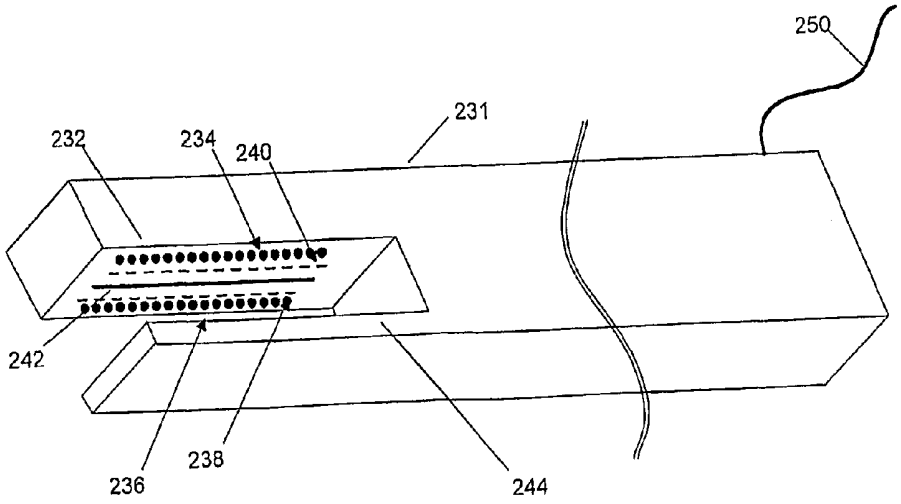


Figure 2a



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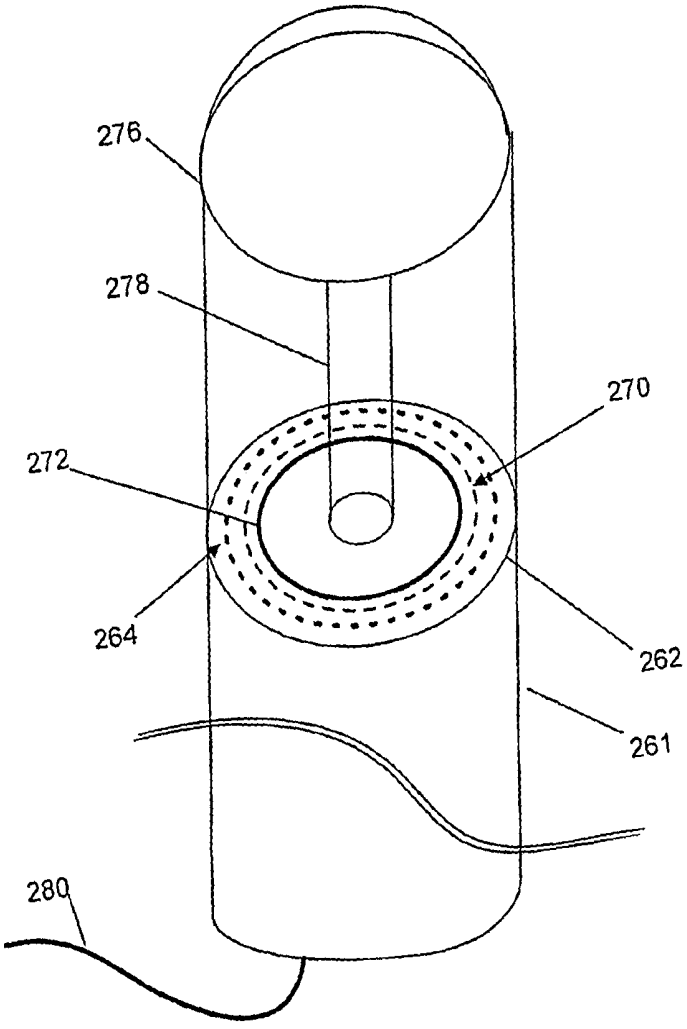


Figure 2c

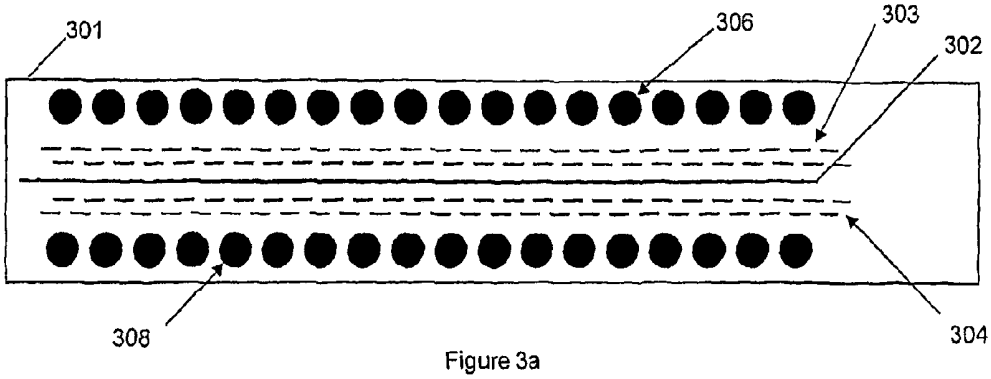


Figure 3a

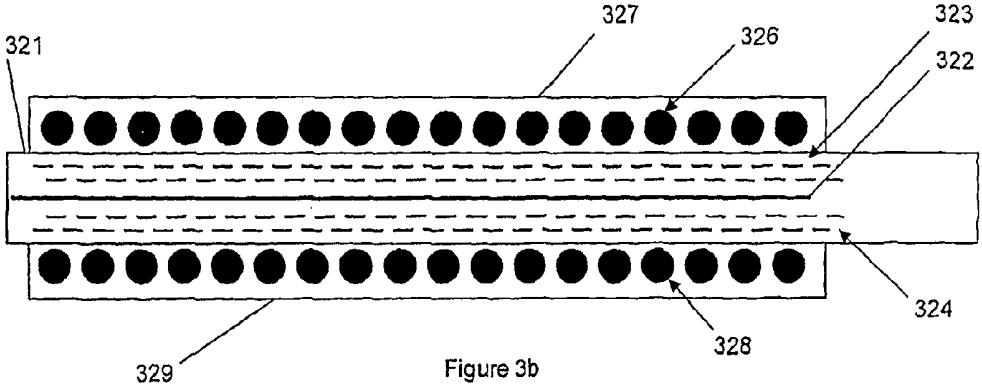


Figure 3b

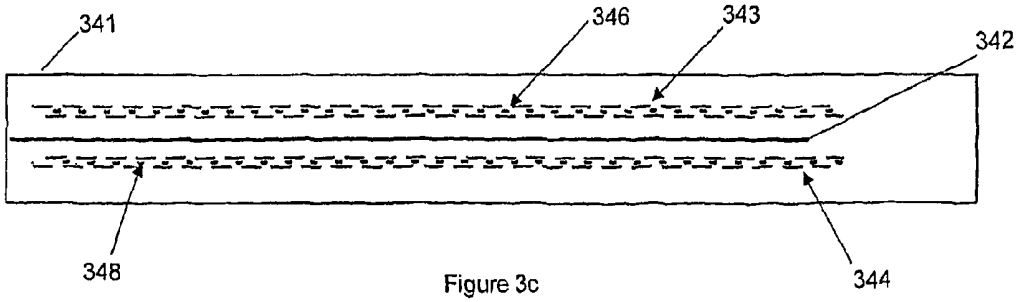
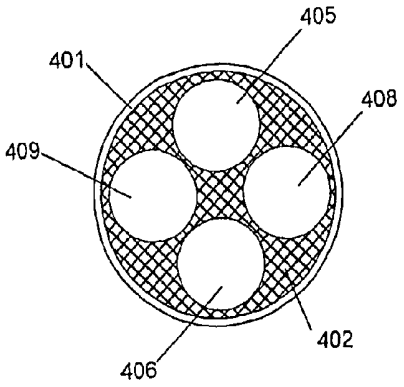


Figure 3c



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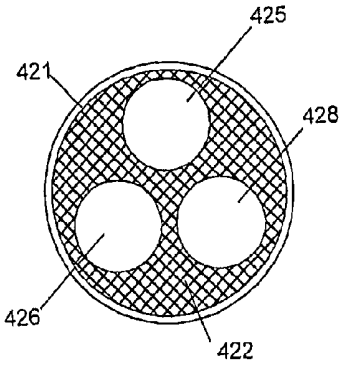
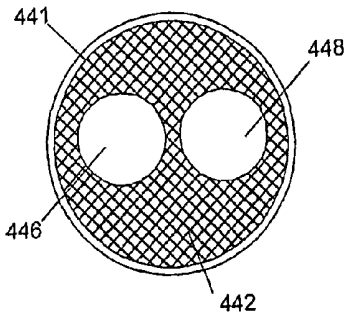


Figure 4b



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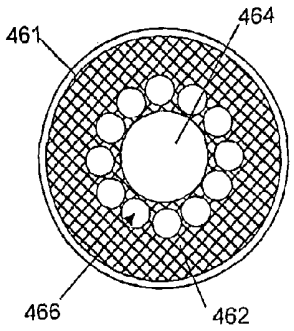


Figure 4d

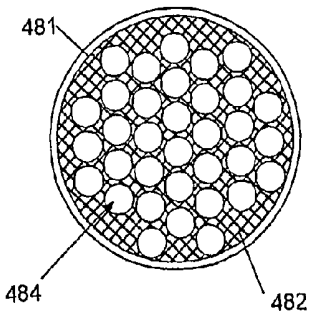


Figure 4e

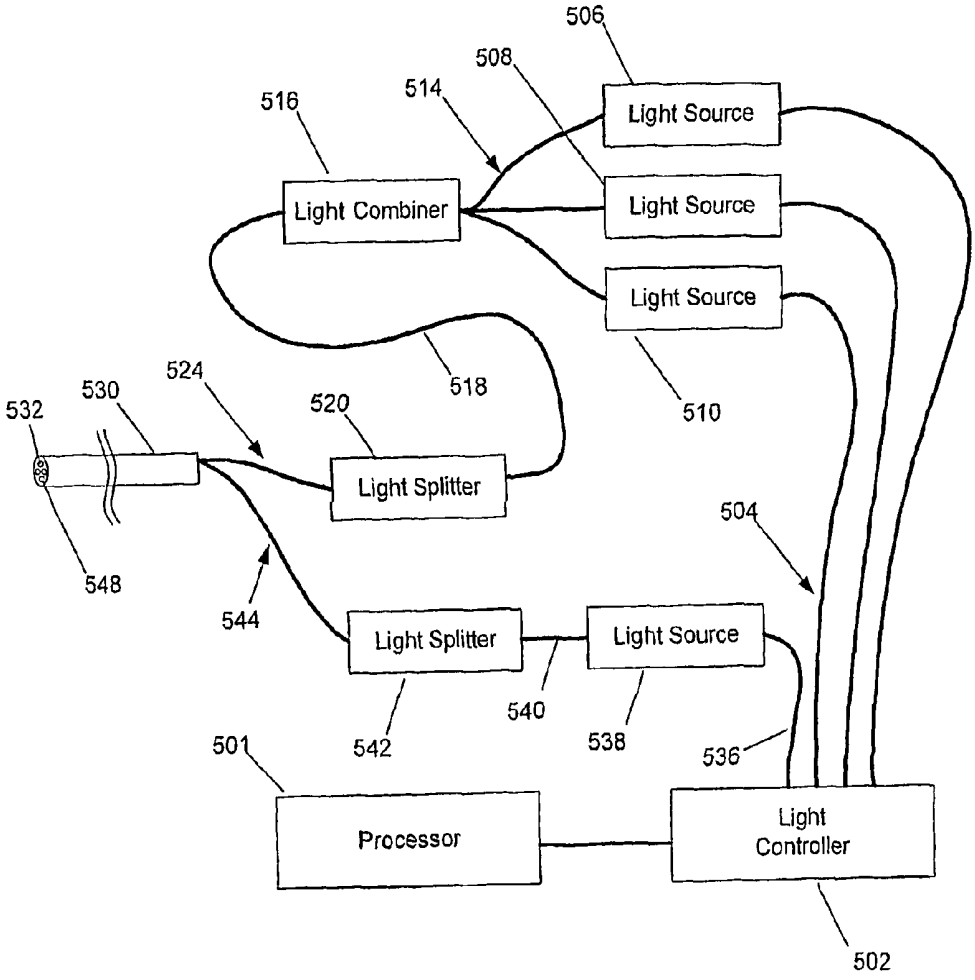

506
508
514
516
Light Source
Light Source
Light Source
Light Combiner
518
510
524
530
532
520
Light Splitter
504
548
544
Light Splitter
Light Source
540
538
542
536
501
Processor
Light
Controller
502

Figure 5a

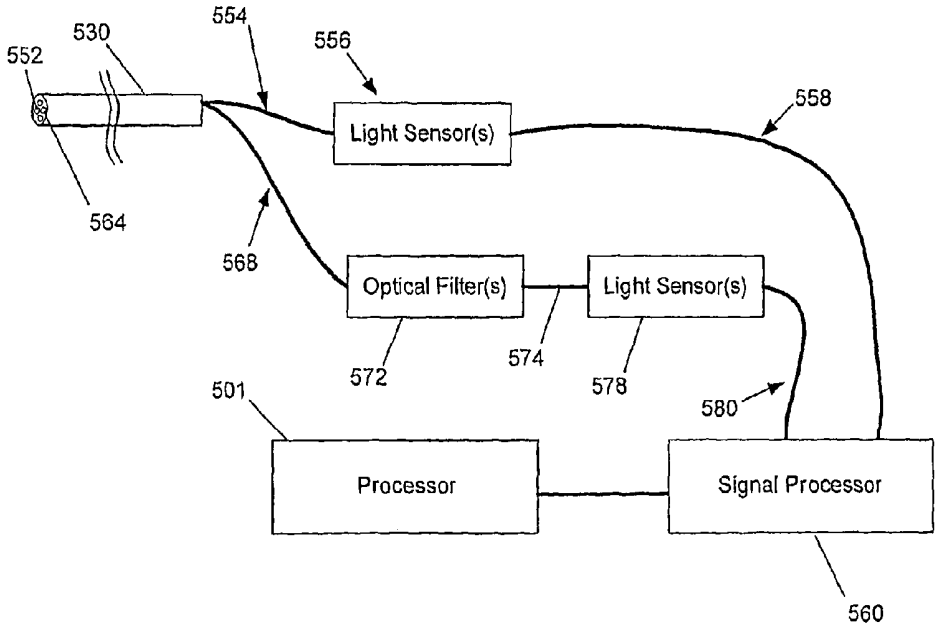

552
530
554
556
558
564
568
Light Sensor(s)
Optical Filter(s)
Light Sensor(s)
572
574
578
580
501
Processor
Signal Processor
560

Figure 5b

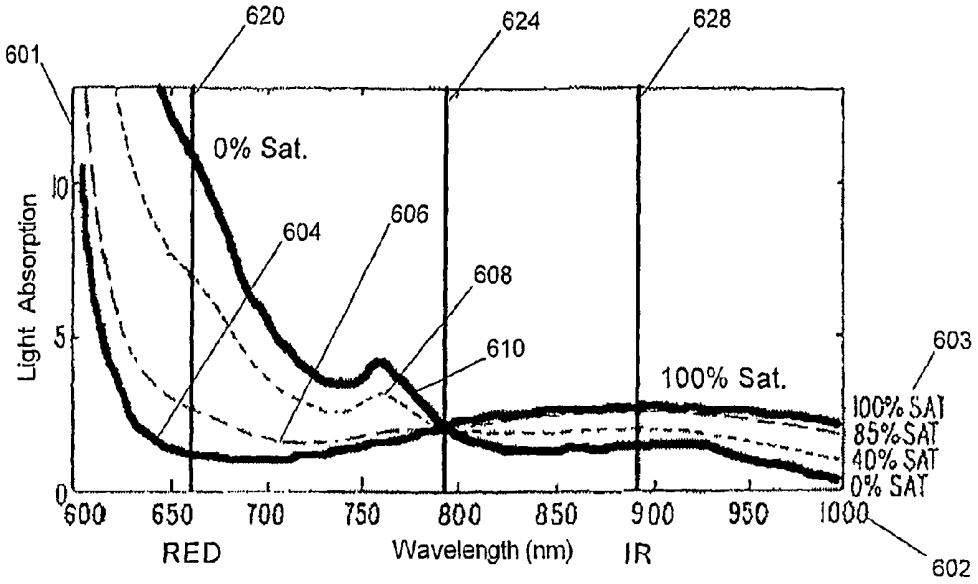


Figure 6a
(Prior Art)

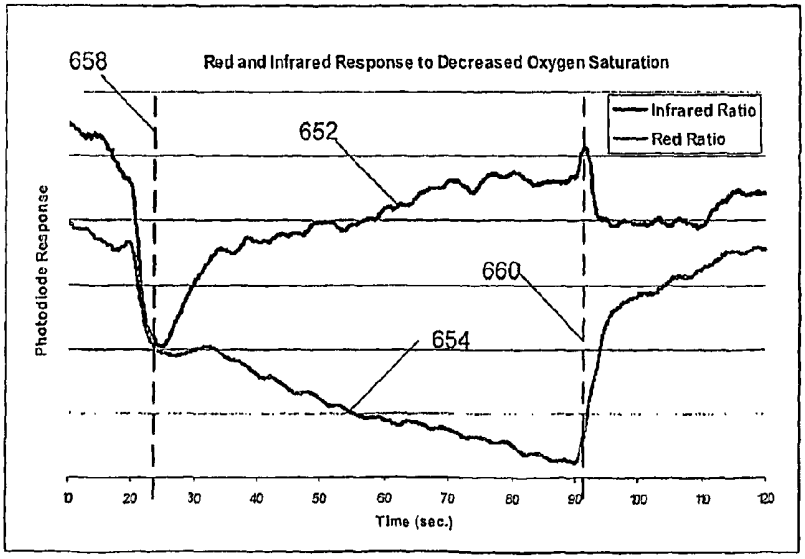


Figure 6b

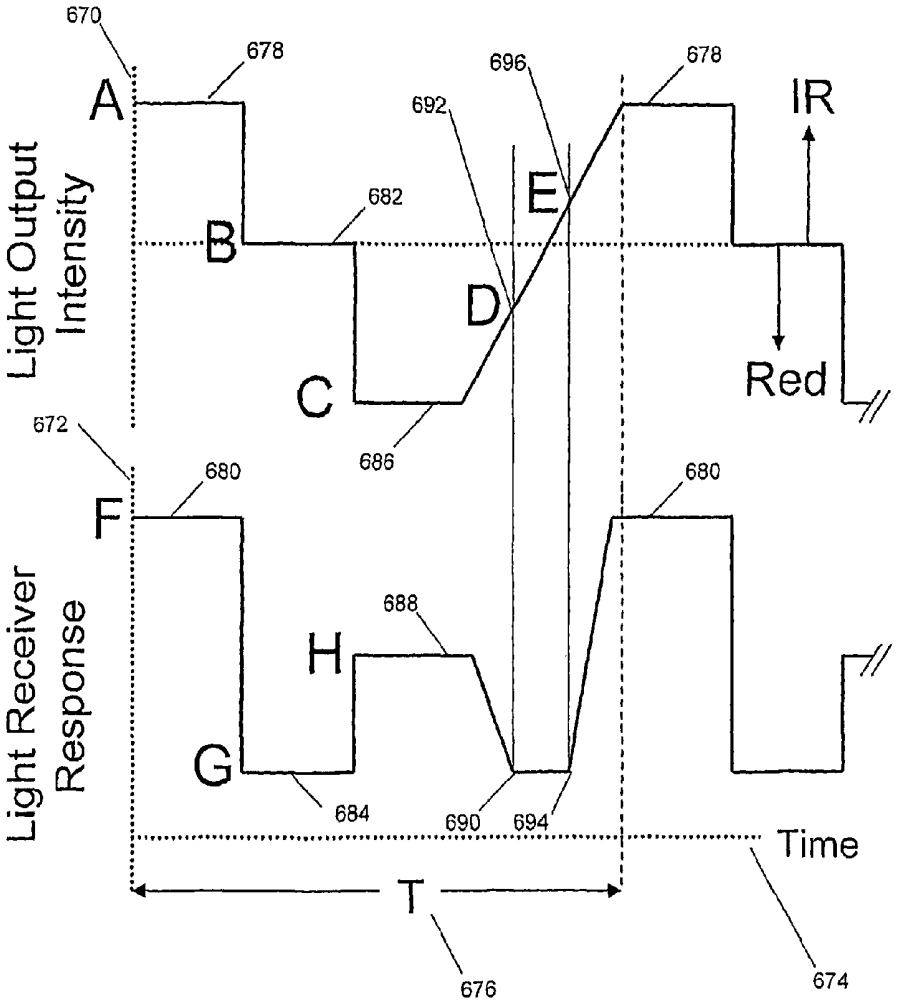

670
678
696
678
692
A
IR
682
E
B
D
C
Red
686
672
680
680
F
688
H
G
684
690
694
Time
T
676
674
Light Output Intensity
Light Receiver Response

Figure 6c

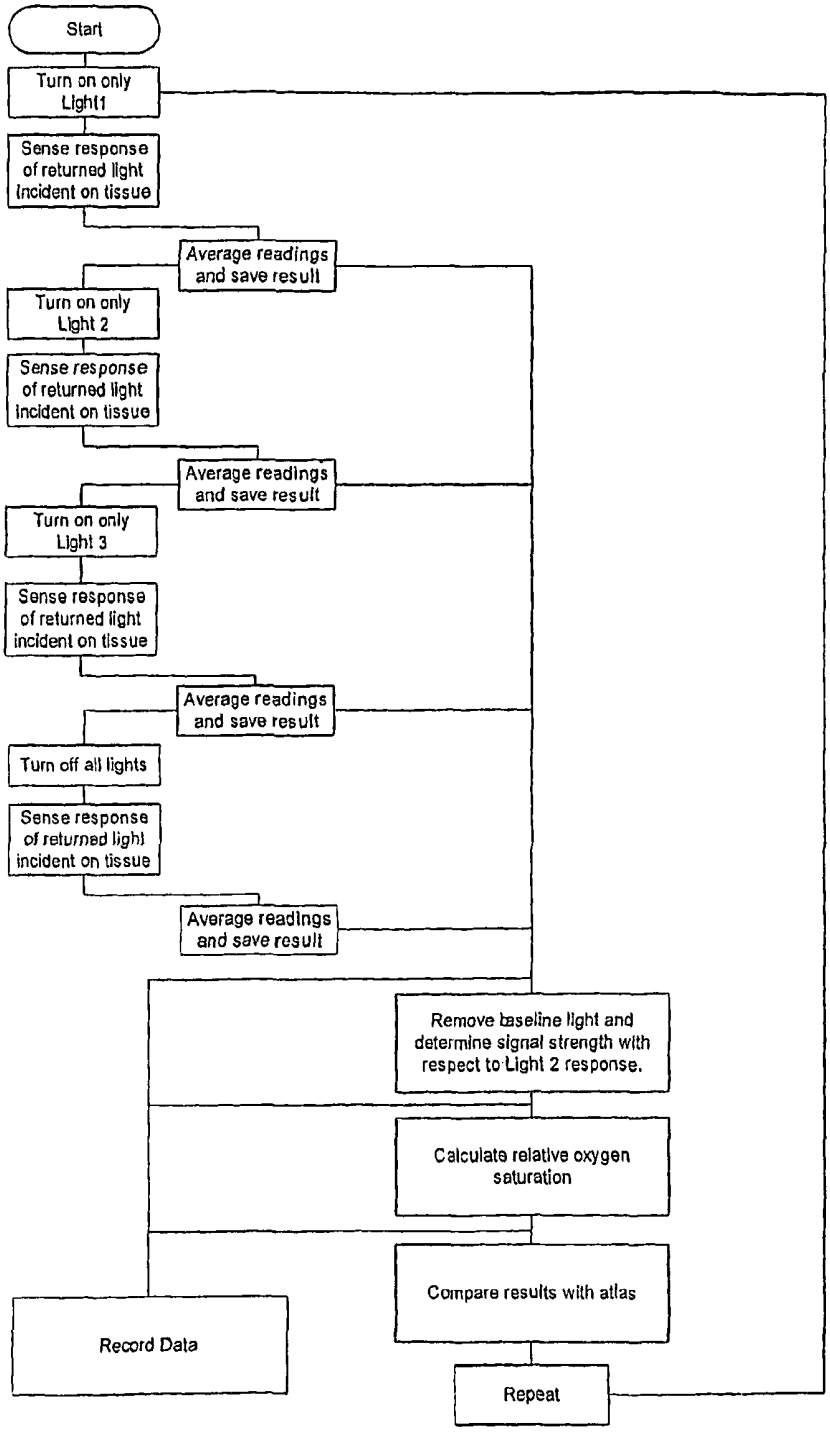

Start
Turn on only Light1
Sense response of returned light incident on tissue
Average readings and save result
Turn on only Light 2
Sense response of returned light incident on tissue
Average readings and save result
Turn on only Light 3
Sense response of returned light incident on tissue
Average readings and save result
Turn off all lights
Sense response of returned light incident on tissue
Average readings and save result
Remove baseline light and determine signal strength with respect to Light 2 response.
Calculate relative oxygen saturation
Compare results with atlas
Record Data
Repeat

Figure 7

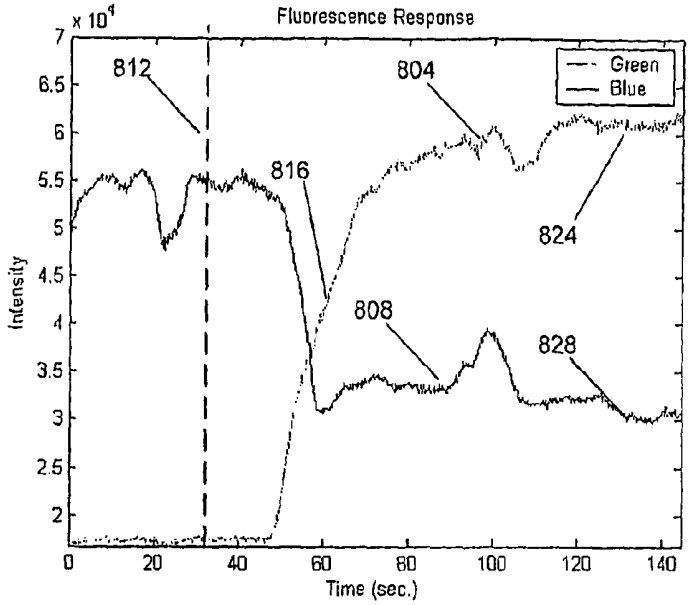


Figure 8a

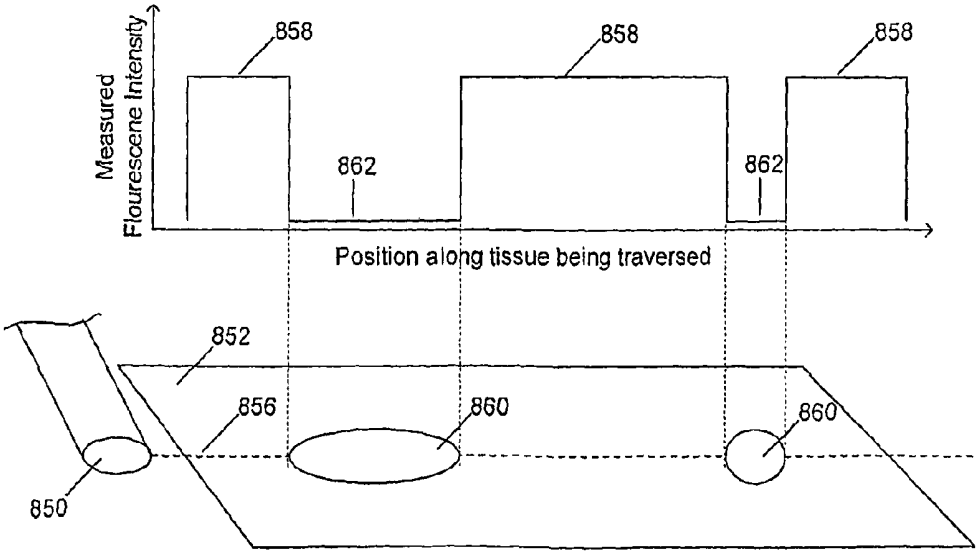


Figure 8b

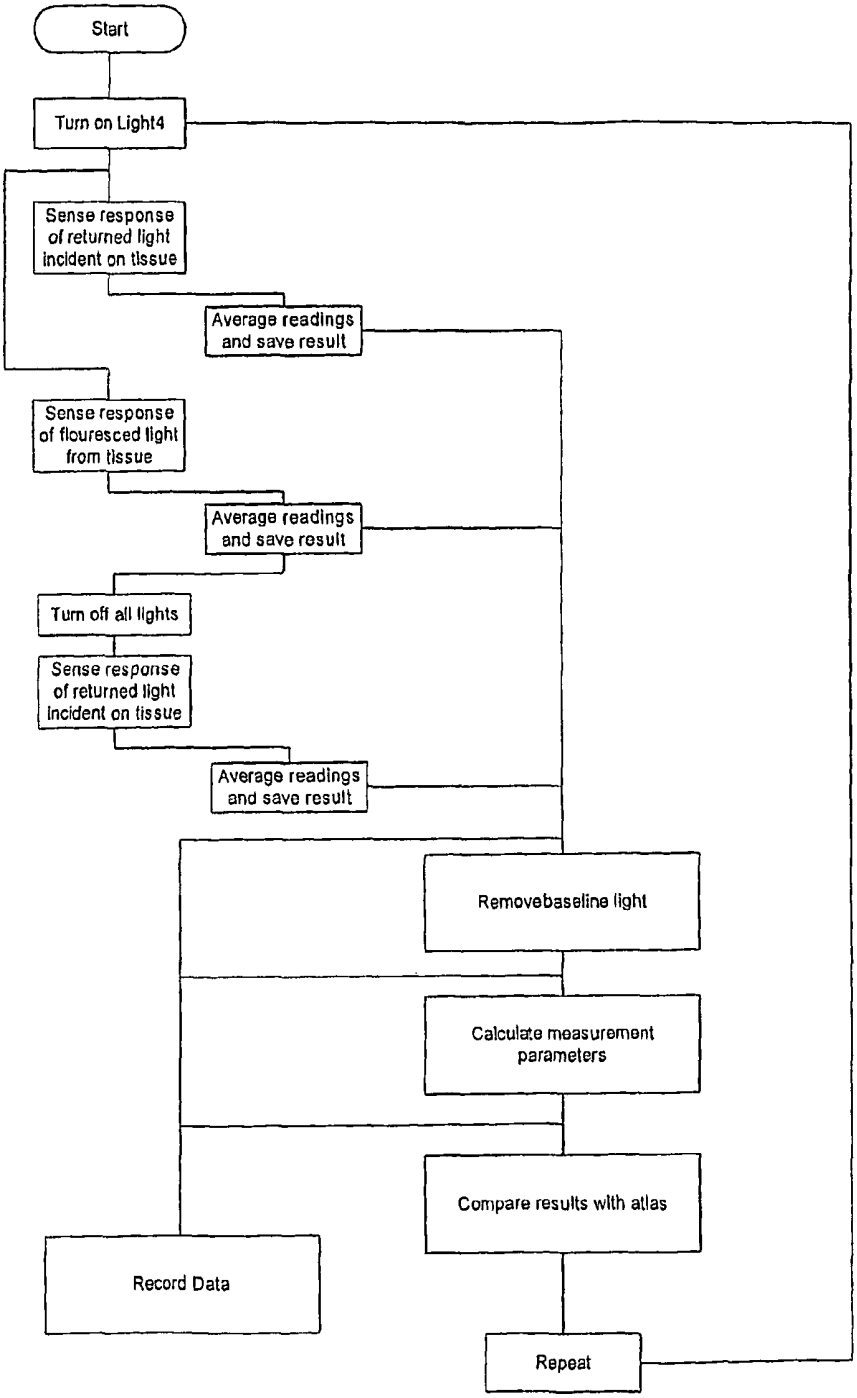
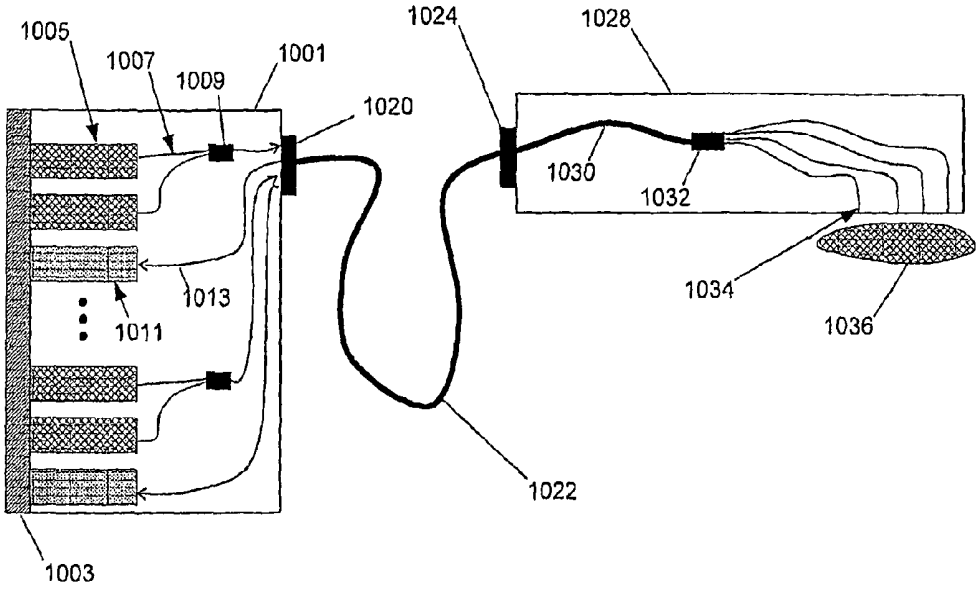

Start
Turn on Light4
Sense response of returned light incident on tissue
Average readings and save result
Sense response of flouresced light from tissue
Average readings and save result
Turn off all lights
Sense response of returned light incident on tissue
Average readings and save result
Removebaseline light
Calculate measurement parameters
Compare results with atlas
Record Data
Repeat

Figure 9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1007
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1013
1011
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1036
1022
1003

Figure 10a

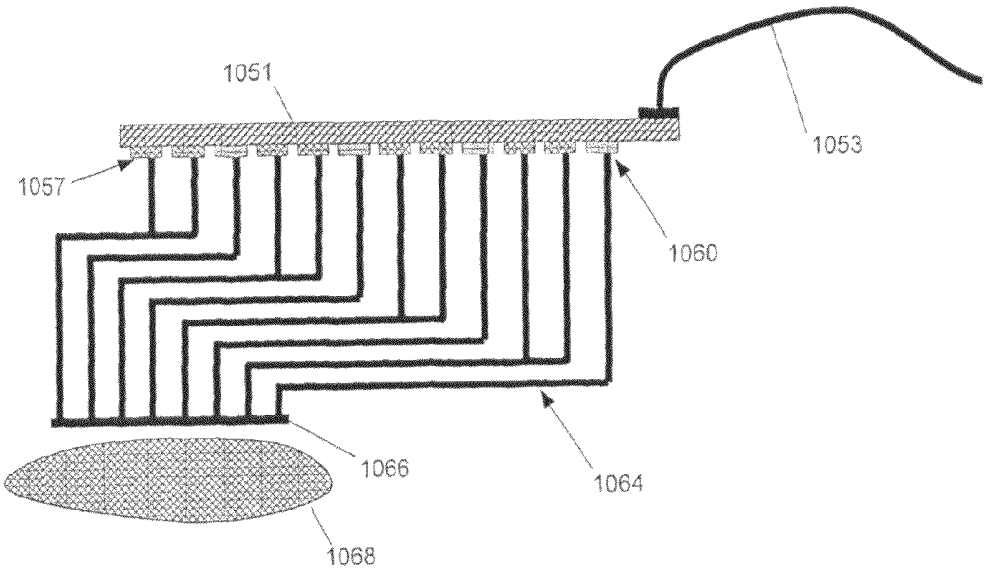


Figure 10b

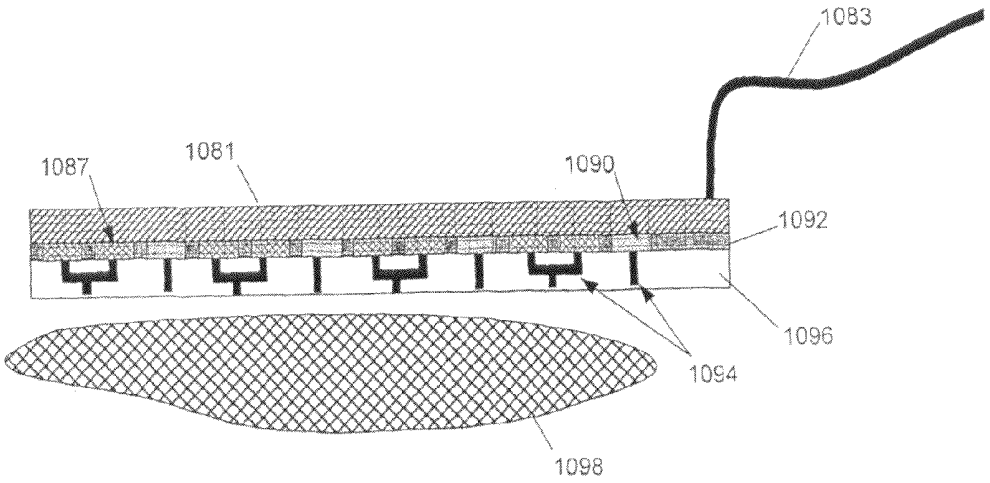


Figure 10c

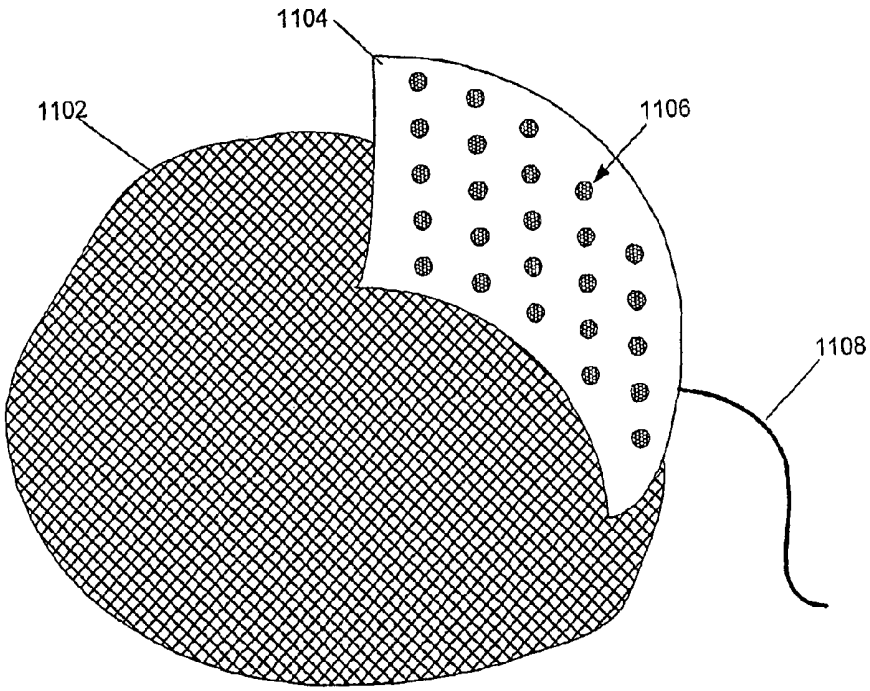


Figure 11a

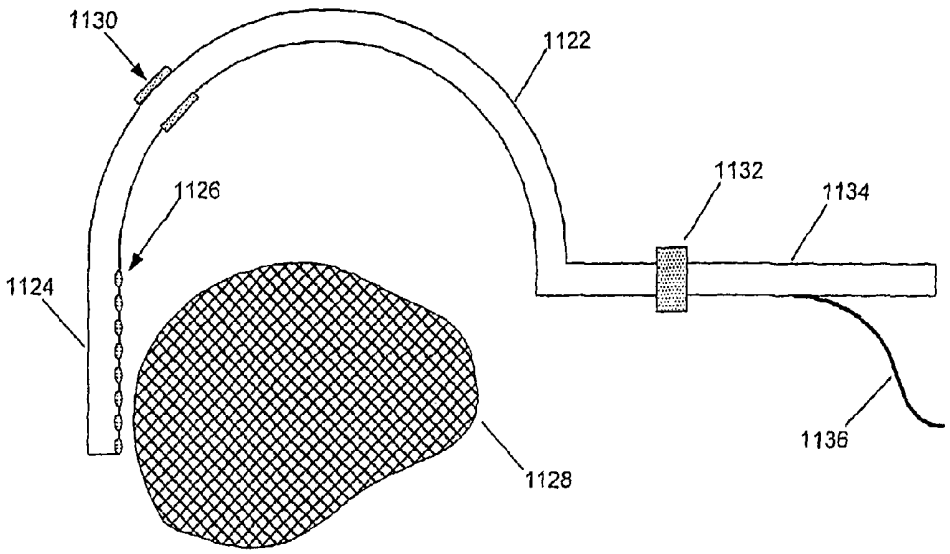
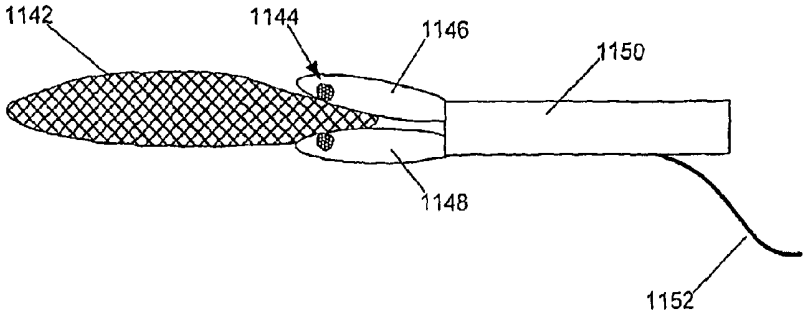


Figure 11b



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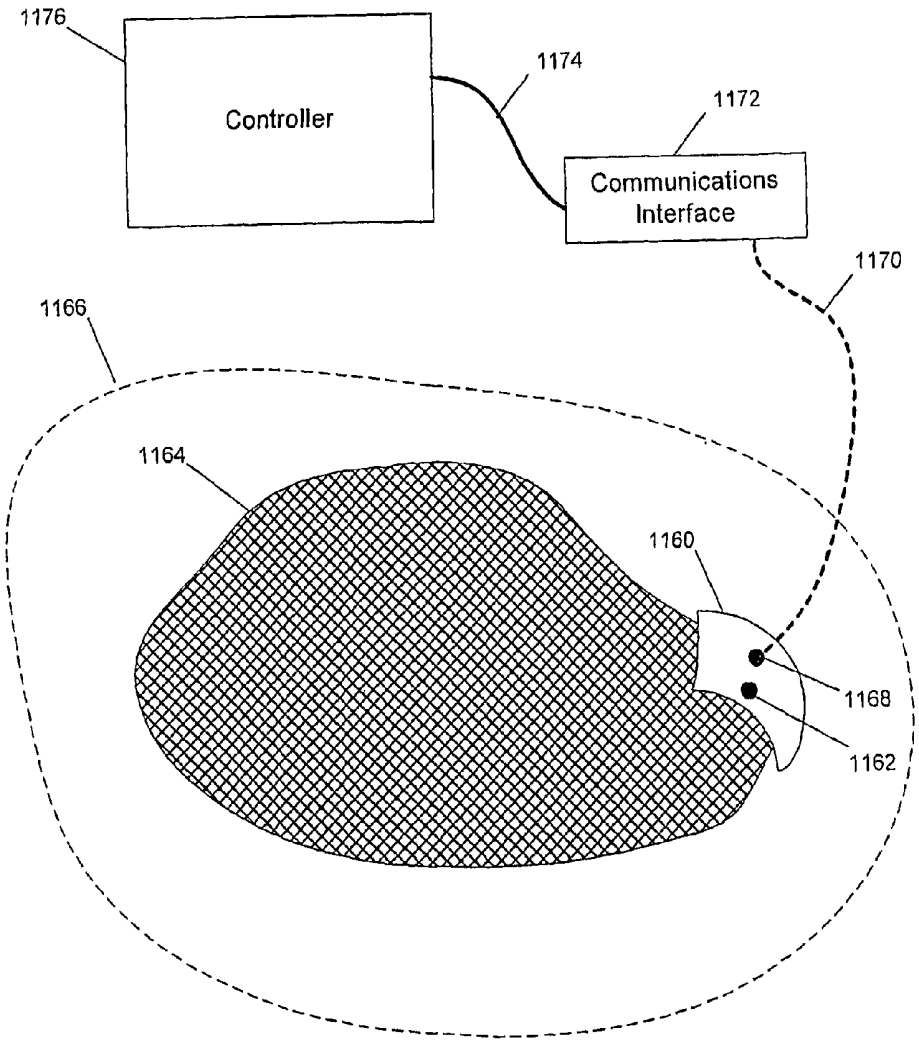

1176
Controller
1174
1172
Communications Interface
1170
1166
1164
1160
1168
1162

Figure 11d

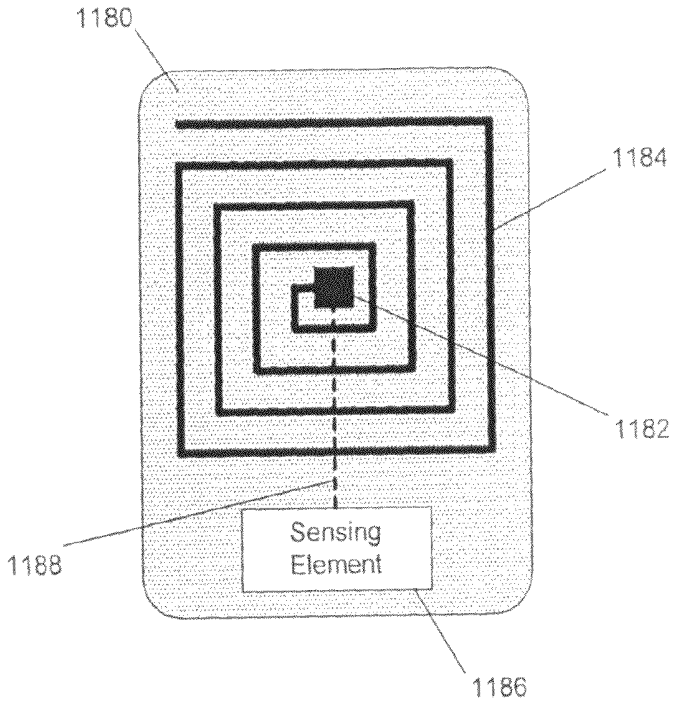


Figure 11e

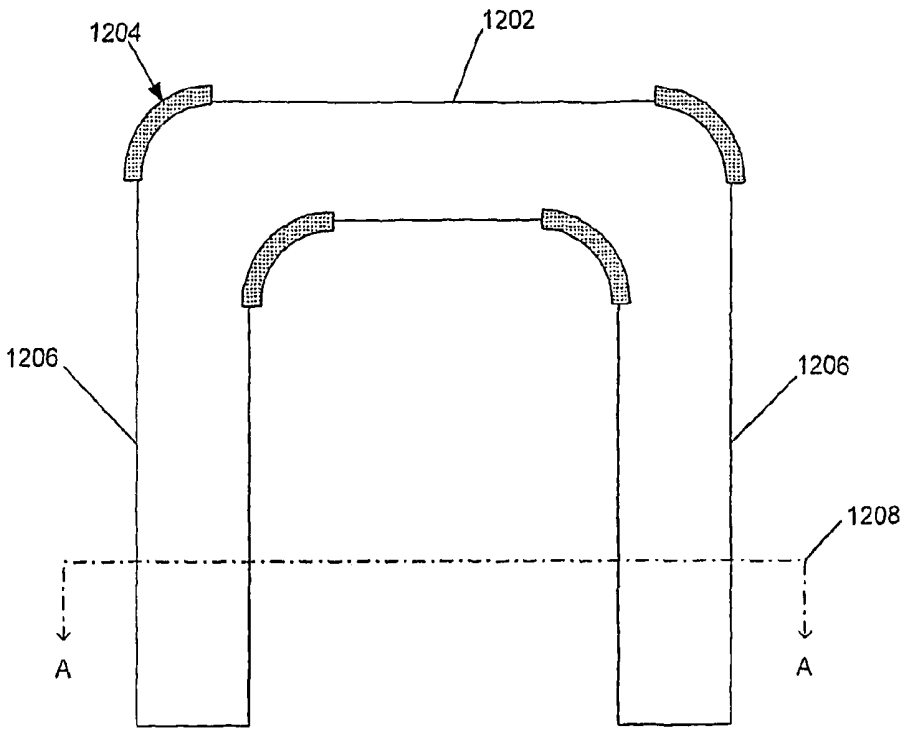
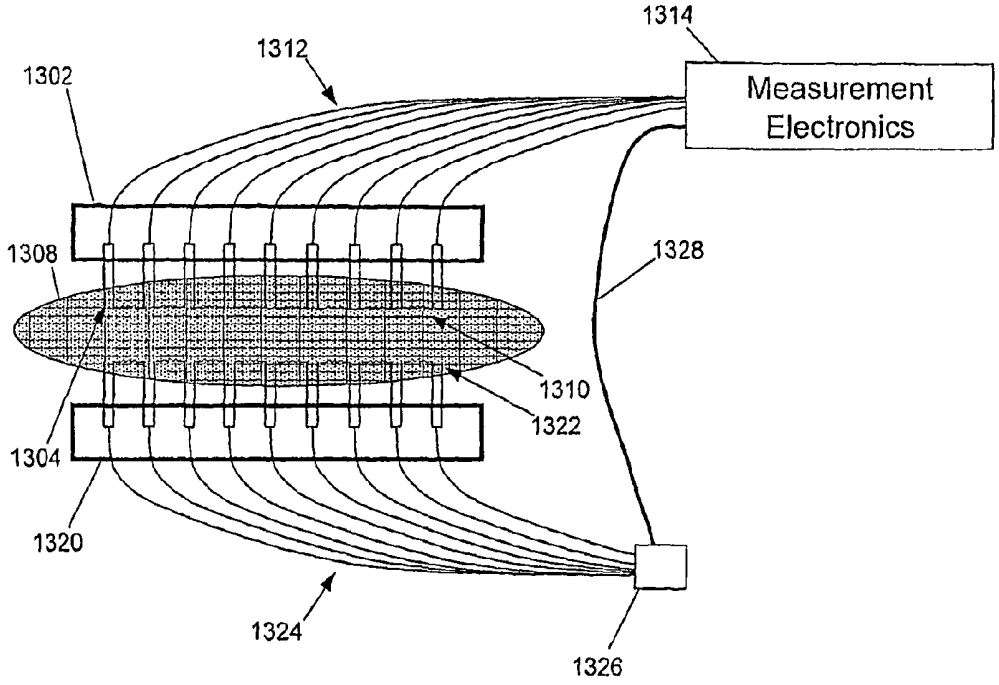


Figure 12a

Figure 12b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1312
1302
Measurement Electronics
1308
1328
1310
1322
1304
1320
1324
1326

Figure 13a

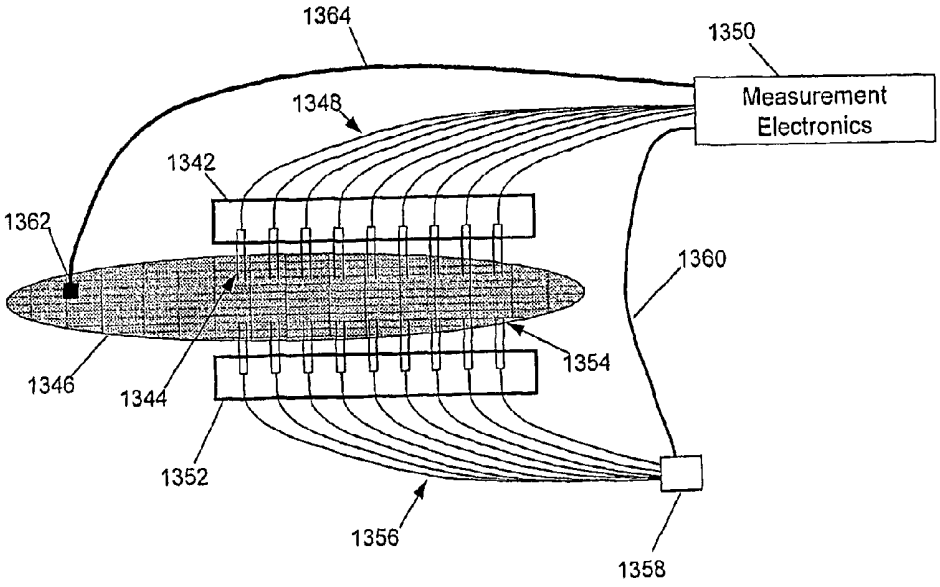
1364
1350
Measurement Electronics
1348
1342
1362
1360
1354
1346
1344
1352
1356
1358

Figure 13b

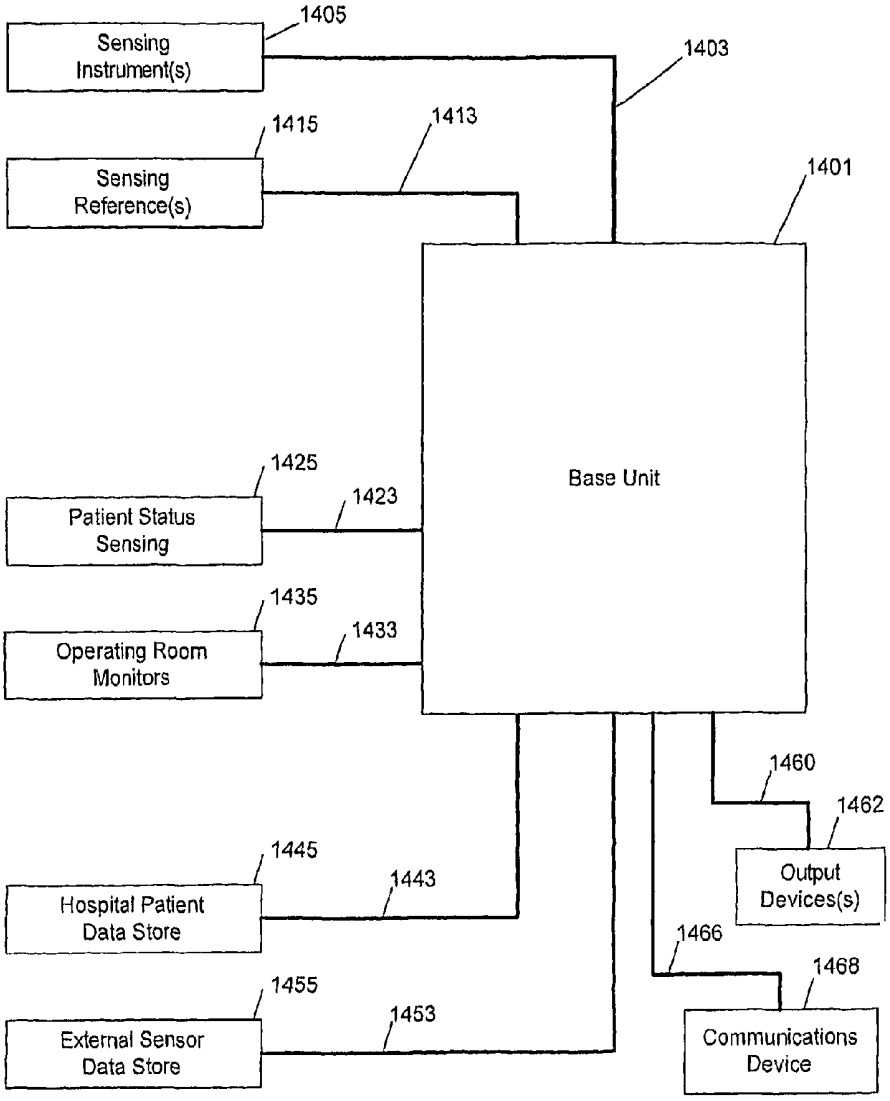
1405
Sensing Instrument(s)
1403
1415
1413
Sensing Reference(s)
1401
Base Unit
1425
1423
Patient Status Sensing
1435
1433
Operating Room Monitors
1460
1462
Output Devices(s)
1445
1443
Hospital Patient Data Store
1466
1468
1455
1453
External Sensor Data Store
Communications Device

Figure 14

SURGICAL INSTRUMENTS WITH SENSORS FOR DETECTING TISSUE PROPERTIES, AND SYSTEM USING SUCH INSTRUMENTS

RELATED APPLICATIONS

This application is the U.S. National Phase under 35 U.S.C. §371 of International Application No. PCT/US2006/013985, filed on Apr. 14, 2006, which in turn claims the benefit of U.S. Provisional Application No. 60/671,872, filed on Apr. 15, 2005 and U.S. Provisional Application No. 60/766,359, filed on Jan. 12, 2006, the disclosures of which Applications are incorporated by reference herein.

FIELD OF THE INVENTION

The present invention relates to surgical instruments, specifically to surgical instruments with sensors used to detect properties of biological tissue, and a system for exploiting the information gathered by the sensors.

BACKGROUND ART

A living organism is made up of cells. Cells are the smallest structures capable of maintaining life and reproducing. Cells have differing structures to perform different tasks. A tissue is an organization of a great many similar cells with varying amounts and kinds of nonliving, intercellular substances between them. An organ is an organization of several different kinds of tissues so arranged that together they can perform a special function.

Surgery is defined as a branch of medicine concerned with diseases requiring operative procedures.

Although many surgical procedures are successful, there is always a chance of failure. Depending on the type of procedure these failures can result in pain, need for re-operation, extreme sickness, or death. At present there is no reliable method of predicting when a failure will occur. Most often the failure occurs after the surgical procedure has been completed. Failures of surgical procedures can take many forms. The most difficult failures to predict and avoid are those that involve biological tissue. This difficulty arises for three distinct reasons. Firstly, the properties that favor the continued function of biological tissue are very complex. Secondly, these properties are necessarily disrupted by surgical manipulation. Finally, the properties of biological tissues vary between people.

During a surgical operation, a variety of surgical instruments are used to manipulate biological tissues. However, traditional surgical instruments do not have the ability to obtain information from biological tissues. Obtaining information from the biological tissues that surgical instruments manipulate can provide a valuable dataset that at present is not collected. For example, this dataset can quantitatively distinguish properties of tissues that will result in success or failure when adapted to specific patient characteristics.

Surgical instruments that incorporate sensors onto the instruments' working surfaces are described, e.g., in U.S. patent application Ser. No. 10/510,940 and in U.S. Pat. No. 5,769,791. The instruments described in the prior art have the ability to sense tissue properties; however, their utility is limited by an inability to account for the multitude of differences that exist between patients. This limitation of the prior art is clearly illustrated by the fact that the instruments generate feedback after sensor signals are compared to a fixed dataset within the device. Thus, the prior art instruments have

no means of adapting to patient-specific characteristics that are of utmost importance in avoiding surgical procedure failure.

There exists a need for a system and methodology for using the information gathered by surgical instruments having sensors in an adaptive, patient-specific manner. There also exists a need for instruments having sensors that are useful for monitoring a patient's condition during and after surgery.

SUMMARY OF THE INVENTION

An advantage of the present invention is a system which generates real time, patient specific procedural guidance for predicting success of a surgical procedure, and avoiding or detecting failure of the procedure. Another advantage of the present invention is a system which records data across the entire patient encounter including pre-operative, intra-operative and post-operative periods, as well as immediate, acute, short term, and long term outcomes both locally in hospital-based units as well as remotely in a data repository.

A further advantage of the present invention is a system which provides expert procedural guidance based upon patient specific data gained from personal medical history, patient status monitoring equipment, surgical instruments incorporating sensors on the instrument's working surface, reference sensors placed about the patient, and implanted sensors placed before, during or after the procedure.

A still further advantage of the present invention is a system which generates patient specific expert guidance in optimizing surgical procedures based upon statistically matched data from a central repository. Yet another advantage of the present invention is a system which adapts its guidance based on continuously updated, statistically significant data.

According to the present invention, the foregoing and other advantages are achieved in part by a system comprising a surgical instrument having a sensor for generating a signal indicative of a property of a subject tissue of a patient; a signal processor for receiving the signal and converting the signal into a current dataset; a memory for storing the current dataset; and a processor. The processor is configured to compare the current dataset with other datasets previously stored in the memory, and to assess a physical condition of the subject tissue or guide a current procedure being performed on the tissue, responsive to the comparison.

Another aspect of the present invention is a system comprising a surgical instrument comprising an incident light source and a sensor for using incident light from the light source to generate a signal indicative of fluorescence of a subject tissue into which a fluorescent medium has been introduced; and a processor configured to receive the signal and to determine a tissue characteristic of the subject tissue responsive to the response of the fluorescence as indicated by the signal.

A further aspect of the present invention is a sensor consisting essentially of a rigid or flexible substrate and a plurality of sensing elements mounted to the substrate for monitoring a property of a living tissue.

A still further aspect of the present invention is a surgical fastening device comprising a sensor for measuring properties of and interaction with a living tissue on the fastening device.

A further aspect of the present invention is a system comprising a surgical instrument having a sensor for generating a signal indicative of a property of a subject tissue of a patient; a reference measurement instrument having a sensor for measuring a reference tissue and generating a reference measurement signal; a signal processor for receiving the signal and

converting the signal into a current dataset, and for receiving the reference measurement signal and converting it into a current reference dataset; a memory for storing the current dataset and the current reference dataset; and a processor. The processor is configured to compare the current dataset with the current reference dataset, and to assess a physical condition of the subject tissue and/or guide a current procedure being performed on the tissue, responsive to the comparison.

Another aspect of the present invention is a system for monitoring a living tissue of a patient's body, comprising a sensor implantable in the patient's body for generating a signal indicative of a property of the tissue; a controller for receiving the signal outside the patient's body; and a communications interface for communicating the signal from the sensor to the controller.

Additional advantages of the present invention will become readily apparent to those skilled in this art from the following detailed description, wherein only selected embodiments of the present invention are shown and described, simply by way of illustration of the best mode contemplated for carrying out the present invention. As will be realized, the present invention is capable of other and different embodiments, and its several details are capable of modifications in various obvious respects, all without departing from the invention. Accordingly, the drawings and description are to be regarded as illustrative in nature, and not as restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

Reference is made to the attached drawings, wherein elements having the same reference numeral designations represent like elements throughout, and wherein:

FIG. **1** is a block diagram of a sensing surgical instrument system according to an embodiment of the present invention.

FIG. **2***a* shows a right angle surgical stapler according to an embodiment of the present invention.

FIG. **2***b* shows a linear surgical stapler according to an embodiment of the present invention.

FIG. **2***c* shows a circular surgical stapler according to an embodiment of the present invention.

FIG. **3***a* shows sensing elements situated on a staple side outside of the staple lines of a surgical stapler according to an embodiment of the present invention.

FIG. **3***b* shows sensing elements situated in a sleeve fixed to a stapler head of a surgical stapler according to an embodiment of the present invention.

FIG. **3***c* shows sensing elements interleaved with staples in a surgical stapler according to an embodiment of the present invention.

FIGS. **4***a*-**4***e* show fiber configurations of an optical sensor tip according to embodiments of the present invention.

FIG. **5***a* is a block diagram of a configuration for transmitting light for the optical sensor of FIGS. **4***a*-**4***e*.

FIG. **5***b* is a block diagram of a configuration for receiving light for the optical sensor of FIGS. **4***a*-**4***e*.

FIG. **6***a* is a graph showing the relationship between light absorption and incident wavelength for varying tissue oxygen saturation.

FIG. **6***b* is a graph showing an example of light absorption in tissue during de-oxygenation and re-oxygenation.

FIG. **6***c* is a timing diagram for an oximetry-type algorithm according to an embodiment of the present invention.

FIG. **7** is a flowchart for oximetry-type oxygenation sensing according to an embodiment of the present invention.

FIG. **8***a* is a graph showing a response to incident light and fluoresced light as fluorescent dye is introduced into a living tissue.

FIG. **8***b* shows a simulated representative fluorescent sensor response as the sensor traverses perfused and non-perfused tissue according to an embodiment of the present invention.

FIG. **9** is a flowchart for fluorescence sensing according to an embodiment of the present invention.

FIG. **10***a* illustrates a system according to an embodiment of the present invention with light sources and receivers external to an instrument.

FIG. **10***b* illustrates a system according to an embodiment of the present invention with light sources, light receivers, and light guides internal to an instrument.

FIG. **10***c* illustrates a system according to an embodiment of the present invention with micro fabricated internal light sources, light receivers, and light guides.

FIG. **11***a* illustrates a sensor configuration according to an embodiment of the present invention where sensing elements are situated on a flexible substrate.

FIG. **11***b* illustrates a sensor configuration on a surgical retractor for open surgery according to an embodiment of the present invention.

FIG. **11***c* illustrates a sensor configuration on a grasper for minimally invasive, laparoscopic surgery according to an embodiment of the present invention.

FIG. **11***d* illustrates a sensor configuration where sensors are implanted into the body and transmit data wirelessly according to an embodiment of the present invention.

FIG. **11***e* illustrates a remotely powered integrated sensor and wireless transmitter according to an embodiment of the present invention.

FIG. **12***a* shows a surgical staple or clip with sensing capabilities according to an embodiment of the present invention.

FIG. **12***b* is a cross-sectional view the sensing staple or clip of FIG. **12***a*.

FIG. **13***a* illustrates a system according to an embodiment of the present invention where the staples or clips measure electrical impedance.

FIG. **13***b* illustrates a system according to an embodiment of the present invention where staples or clips and a reference sensor perform electric electrical stimulation and electrical activity sensing.

FIG. **14** is a block diagram of an intelligent expert system according to an embodiment of the present invention with integrated sensing, monitoring, data storage, outcome prediction, and display capabilities.

DESCRIPTION OF THE INVENTION

Conventional surgical instruments having sensors for measuring tissue properties have no means of adapting to patient-specific characteristics that are of utmost importance in avoiding surgical procedure failure. The present invention addresses and solves these problems stemming from conventional sensing surgical instruments.

According to the present invention, a system provides expert procedural guidance based upon patient specific data gained from surgical instruments incorporating sensors on the instrument's working surface, one or more reference sensors placed about the patient, sensors implanted before, during or after the procedure, the patient's personal medical history, and patient status monitoring equipment. In certain embodiments, the system records data across the entire patient encounter including pre-operative, intra-operative and post-operative periods, as well as immediate, acute, short

term, and long term outcomes both locally in hospital-based units as well as remotely in a data repository.

In other embodiments, the inventive system generates patient-specific expert guidance in optimizing surgical procedures based upon statistically matched data from a central repository, and/or adapts its guidance based on continuously updated, statistically significant data.

The present invention will now be described in detail with reference to FIGS. **1-14**.

FIG. **1** schematically shows a representative sensing surgical instrument system with adaptively updating algorithms according to an embodiment of the present invention. This embodiment specifically depicts a sensing surgical stapler **101** for measuring properties of tissue **102**. One or more other similarly instrumented well-known surgical instruments including, but not limited to, clip appliers, graspers, retractors, scalpels, forceps, electrocautery tools, scissors, clamps, needles, catheters, trochars, laparoscopic tools, open surgical tools and robotic instruments may be integrated into the system instead of or in addition to stapler **101**. Sensing elements **104** reside on the stapling element side **105** and/or the anvil side **106**. The stapler is coupled via a conventional optical, electrical, or wireless connection **108** to a processing and control unit **120**.

The system of FIG. **1** includes one or more reference measurement points, internal or external, invasive, minimally invasive or noninvasive, intracorporeal or extracorporeal. One example of such a reference measurement sensor, shown in the form of a clip **110**, grasps reference tissue **112**, typically healthy tissue in the same patient serving as a reference for use as a patient-specific baseline measurement. Sensing elements **111** are on one or both sides of the jaws **116** and **117**. Reference sensor **110** need not be a clip, but can be a probe or any other sensing instrument or device. Reference sensor **110** is coupled via a conventional optical, electrical, or wireless connection **118** to processing and control unit **120**.

In certain embodiments of the inventive system of FIG. **1**, optical signals are generated by the sensor controller **123**, light returning from the distal end of the sensors is received by sensing unit **121**, and the associated signals are conditioned in signal processor **122** and converted into a dataset, which is stored in a memory, such as database **131**. A processor **124**, is coupled to both the input and output datasets and compares the information to determine characteristics of the tissue, the patient, and the procedure. The processor **124** comprises, for example, a conventional personal computer or an embedded microcontroller or microprocessor. Control and monitoring of the sensor outputs **123** and inputs **121** respectively is performed with conventional commercially available or custom-made data acquisition hardware that is controlled by the processor **124**. Signal processor **122** is integral with processor **124**, or is a conventional digital or analog signal processor placed between the sensor input **121** and the processor **124**. Depending on the sensing modality, the sensor data is translated into information that relates to tissue properties. In one exemplary optical sensing embodiment, oximetry-type techniques are used to convert the relative absorption of different wavelengths of light into an oxygen saturation percentage of hemoglobin in the blood. In another optical sensing modality, fluorescence response due to a fluorescent medium that has been introduced into the body is measured, and characteristics of the response including the intensity rise time and steady state value are indicative of the blood flow in the tissue in question. All raw data and processed results are recorded by a recorder **130**. This dataset can include measurements made preoperatively, intra operatively, and/or post operatively, as well as pre procedurally (before actuation of the device), at the time of the procedure (as the device is actuated), and/or post procedurally (immediately and delayed after actuation of the device). In addition, outcomes are recorded; these outcomes include immediate outcomes (during procedure), acute outcomes (within 24 hours), short term outcomes (within 30 days), and long term outcomes. Post procedure outcomes can be either quantitative measurements from implantable or other sensors, lab results, follow up imaging or other sources, or they can be qualitative assessments of the patient and the procedure by a medical professional.

A dynamically updated database of past patient encounters **131** is coupled with the processor **124** for creating a decision about tissue health based on previous knowledge. Database **131** includes information about the current patient and also data from previous patients that is used to make an informed decision about the tissue health and the likelihood of success of a procedure. The system offers solutions to the medical team to optimize the chance of procedural success. The collected dataset including sensor data and outcomes from the current procedure are added to database **131** to help make more informed future decisions. Outcomes can be added, after follow up visits with the patient at a later date, into either the system or a external database from an external source. The database **131** may be stored locally in base unit **120** or externally, but is updated by and sends updates to a central database that serves other base units **120** via a communications device **138**, such as a conventional modem, an internet connection, or other network connection. Further, recorder **130** can be linked to a central repository for patient information to include some or all recorded information with medical history in patient records.

Large amounts of data are collected for each patient. The database **131** contains all of the collected information and the corresponding outcomes, or a statistically significant subset of the collected data and patient outcomes. The database, or a subset thereof, acts as a statistical atlas of predicted outcomes for a given set of sensor inputs. Conventional techniques are used for determining the relationship between the current sensor readings and those of the atlas, to interpolate or extrapolate a predicted outcome or likelihood of procedure success or failure. One technique well-known in the art represents the current patient's sensor and other inputs in a vector; the similar datasets from the atlas or database are represented in a similar form as a set of vectors. The "distance" between the current patient data and each set of previously stored data is determined; distance can be determined as the standard Euclidean distance between the vectors; i.e. the 2-norm of the difference between the vectors, or other distance measures as known in the art including other norms and the Mahalanobis distance. The difference between the vectors, or the vectors themselves, can be multiplied by a weighting matrix to take into account the differences in the significance of certain variables and sensor readings in determining the outcome. The set of distances of the current dataset from the previously stored sets is used as a weighting factor for interpolating or extrapolating the outcome, likelihood of success or failure, or other characteristics of the previously stored datasets. In another well-known technique, methods typically used in image processing and statistical shape modeling for deforming a statistical atlas can be incorporated. A base dataset generated from the database of previously collected datasets and the most statistically significant modes of deformation are determined, where the previously collected datasets act as training datasets. The magnitudes of the deformation for each mode are determined to best match the atlas model to the current dataset. The magnitudes are then used to deform the set of previous out-

comes in a similar fashion, or otherwise interpolate between the previous outcomes by determining how the each outcome is dependent on each mode of deformation, to determine the best fit for the current patient. Other conventional techniques for predicting outcomes based on prior and current datasets are based on determining the similarity between the current dataset with those that were previously acquired from other patients, and using the similarity measure to determine a likelihood of a given outcome responsive to those corresponding to the prior datasets.

Attached to, or integrated directly into, the base control unit **120** is one or more output devices **134**. Output device **134** is used to provide persons performing the procedure information about the physiologic condition of the tissue, and to help guide the procedure. The output device **134** takes information from the sensors, prior data, patient records, other equipment, calculations and assessments, and other information and presents it to the clinician and operating room staff in a useful manner. In one embodiment, the measured information is compared with prior datasets and prior patient outcomes, and the output device displays information to help assess the likelihood of success of a given procedure with the current configuration. The information displayed can simply be a message such as "go ahead as planned" or "choose another site." In another embodiment, the information is encoded in some form of sensory substitution where feedback is provided via forms including, but not limited to, visual, audible, or tactile sensation.

FIGS. **2***a*-**2***c* depict specific stapler configurations according to embodiments of the present invention. FIG. **2***a* depicts a right angle surgical stapler **201**. The stapling element side of the jaws **202** is instrumented with sensing elements **204** and **206** associated with each set of staple lines **208** and **210** which are on both sides of the cutter **212**. In this embodiment, the anvil side of the jaws **214** is not instrumented with sensors. Sensing elements **204** and **206** can be placed on either or both sides of the jaws **202** and **214**. In one embodiment, the stapler is coupled via optical cable **220** to the previously described processing and control unit **120**. This coupling **220** can also be electrical or wireless.

FIG. **2***b* depicts a linear surgical stapler **231** according to an embodiment of the present invention. The stapling element side of the jaws **232** is instrumented with sensing elements **234** and **236** associated with each set of staple lines **238** and **240** which are on both sides of the cutter **212**. In this embodiment, the anvil side of the jaws **214** is not instrumented with sensors. Sensing elements **204** and **206** can be placed on either or both sides of the jaws **232** and **234**. The stapler is coupled via optical cable **250** to the previously described processing and control unit **120**. This coupling **250** is electrical or wireless.

FIG. **2***c* depicts a circular surgical stapler **261** according to an embodiment of the present invention. The stapling element side of the jaws **262** is instrumented with a ring of sensing elements **264** associated the ring of staples lines **270** and outside of the circular cutter **272**. Since the anvil is detachable and connected by pin **278**, in this embodiment, the anvil side of the stapler **276** is not instrumented with sensors. Sensing elements **264** are placed on either or both the stapling element side **264** and the anvil side **276**. The stapler is coupled via optical cable **280** to the previously described processing and control unit **120**. Alternatively, this coupling **280** is electrical or wireless. Other stapler designs or clip appliers are instrumented similarly, with one or more sensors on one or both sides of the jaws.

FIGS. **3***a*-**3***c* show configurations of sensing elements on the surface of a linear stapler according to embodiments of the present invention. These configurations are generalized to any shaped stapler or other surgical instrument. Sensing elements are shown in a linear arrangement; they can be arranged in other patterns including staggered rows, randomized, single sensors and arrays of sensors. FIG. **3***a* shows a linear stapler head **301** with sensing elements **306** and **308** on the outside of staple or clips **303** and **304**, which are outside the cutter **302**. Cutter **302** is optional, and there may be a total of one or more staples, staple lines, or clips. The sensing elements **306** and **308** are situated such that they sense the tissue outside of the staple lines on one or both sides.

FIG. **3***b* shows a linear stapler head **321** according to an embodiment of the present invention. Attached to the stapler or integrated into stapler head **321** is a strip or shell **327** and **329**. This shell can be permanently integrated into the stapler or an addition to the stapler. Thus, it can be a modification to an existing stapler. Enclosed in the sensing shell **327**, **329** are sensing elements **326** and **328**. The stapler comprises one or more staples or clips **323** and **324** and cutters **322**.

FIG. **3***c* shows a linear stapler head **341** with the sensing elements **346** and **348** integrated into the stapler head, according to an embodiment of the present invention. The sensing elements are placed such that they are in line with or integrated between the staples or clips **343**, **344**. Medial to the staples and sensors is an optional cutter **342**. The sensors are placed on one or both sides of the cutter.

FIGS. **4***a*-**4***e* show configurations of optical sensing elements according to embodiments of the present invention where a surgical instrument is coupled to base unit **120** optically. This coupling can also be electrical or wireless with the actual electronic sensing elements placed in the instrument as opposed to an optical coupling from a remote source.

FIG. **4***a* shows an embodiment where the sensing element contains four optical fibers **405**, **406**, **408**, and **409**. These are embedded in a medium **402**, typically optical epoxy, and enclosed in sheath or ferrule **401**. In this embodiment, two optical fibers are used to transmit light into the tissue and two others are used to return light to the receiver in the base unit **120**. The arrangement of the emitting and receiving elements is such that matching emitter/receiver pairs are adjacent or opposing. Further, the same optical fiber can be used to transmit light in both directions. One or more optical fibers are used to transmit light to and from the working surface of the instrument.

FIG. **4***b* shows an optical fiber arrangement with fibers **425**, **426**, and **428** embedded in a medium **422** which is enclosed in a sheath or ferrule **421**. In this embodiment of the invention, two optical fibers are used for transmitting light into the tissue and a single fiber is used to return light to the receiver. FIG. **4***c* shows a similar embodiment where there are two optical fibers **446** and **448** embedded in medium **442** inside of sheath or ferrule **441**. In this embodiment, a single optical fiber transmits all light to the tissue and a single fiber receives light from the tissue.

FIG. **4***d* shows an embodiment where there is a ring of optical fibers **466** that surround optical fiber **464** inside of medium **462** enclosed in sheath or ferrule **461**. The outer ring of fibers **466** is used to transmit light while the inner fiber **464** receives light. Alternatively, the outer ring of fibers **466** can be used to receive light transmitted from the inner fiber **464**.

FIG. **4***e* shows another embodiment of the sensing element which contains a multitude of optical fibers **484** stabilized in a medium **482** enclosed in a sheath or ferrule **481**. The fibers are arranged in an arbitrary or random pattern of light emitters and light receivers. Each fiber is attached to an individual light source or light sensor, and/or more than one fiber is coupled optically to share a light emitter or sensor.

FIG. **5***a* schematically displays a configuration of the light emitting components for a single measurement point in one embodiment of the sensing stapler or other sensing instrument of the invention. A processor **501**, contained in the base unit **120** or onboard the instrument, commands the light controller **502**, which also is located either in the base unit **120** or onboard the instrument. The light controller **502** is coupled to the light sources for one sensing modality by connections **504**. The light sources **506**, **508**, and **510** provide the light that is incident on the tissue **102**. In one embodiment, these light sources are lasers with wavelengths centered at red (near 660 nm), near-infrared (near 790 nm), and infrared (near 880 nm), respectively. This configuration is used for oximetry-type sensing where one wavelength is situated at the isobestic point for light absorption in hemoglobin, one is situated at a greater wavelength, and one is situated at a lesser wavelength. Light sources **506**, **508**, and **510** are one, two, three, or more distinct light emitters and are laser, light emitting diode (LED), or other sources. Alternatively, these distinct light sources are a broadband light source such as a white light. If more than one light source is used, optical couplings **514** connect the sources to a light combiner **516**. If more than one output is required (i.e. more than one measurement point using the same light source), optical coupling **518** takes the light into a light splitter **520**. Optical couplings **524** take the light to the appropriate fiber assembly **530**. Light is transmitted out of the fiber assembly at the fiber end **532** on the tip. This tip is as depicted in FIG. **4***a*.

The light controller **502** controls the light emitter for one or more sensing modalities. In this embodiment, there are two optical sensing modalities: oximetry-type tissue oxygenation sensing and fluorescence sensing. Coupling **536** allows the light controller to control light source **538**. Light source **538** is a high power blue LED with a center wavelength of 570 nm. This light emitter is a laser, LED, or other light source. This source is composed of one or more sources that emit light at one or more wavelengths or a broadband light source emitting at a spectrum of wavelengths. Optical filtering can also be performed on a broadband light source to produce the desired spectral output. The light from light source **538** is coupled optically **540** to a light splitter **542** if more than one measurement point uses the same source. Optical coupling **544** connects the light to the optical cable assembly **530**, and light is emitted at tip **548**.

In another embodiment of the invention, the light from optical fibers **524** and **544** is combined and the light is emitted from an optical fiber assembly as described in FIG. **4***b*, **4***c*, or **4***d* (emitter as fiber **464**). In a further embodiment, the light from optical fibers **524** and **544** is split, or combined and split, into multiple fibers to be used with a cable assembly as shown in FIG. **4***d* (emitters as fibers **466**) or FIG. **4***e*.

FIG. **5***b* schematically displays a configuration of light receiving components for a single measurement point in one embodiment of the sensing stapler or other sensing instrument **101**. Light from the emitter described in FIG. **5***a* is incident upon the tissue being queried and the transmitted and/or reflected light passes into the tip **552** and returns through the optical cable assembly **530**. Optical coupling **554** directs the light to light sensors **556**. In one embodiment, light sensor **556** is an avalanche photodiode. Sensor **556** is, but is not limited to, conventional photodiodes, avalanche photodiodes, CCDs, linear CCD arrays, 2 D CCD arrays, CMOS sensors, photomultipliers tubes, cameras, or other light sensing devices. In a further embodiment, light sensor **556** is a spectrometer or equivalent device that measures light intensity at one or more discrete wavelengths. In a still further embodiment, light sensor **556** is a set of selective photodiodes tuned to the wavelengths of emitted light from light sources **506**, **508**, and **510**. Selective photodiodes are either naturally tuned to specific wavelengths or coupled with an appropriate optical filter. Light sensors **556** are coupled **558** with a signal processor **560**. The signal processor **560** performs filtering, demodulating, frequency analysis, timing, and/or gain adjustment, and/or other signal processing tasks. The signal processor **560** is coupled with the processor **501** where further calculations, analysis, logging, statistical analysis, comparisons with reference, comparisons with database, visualization, notification, and/or other tasks are performed or directed.

Light from the emitter described in FIG. **5***a* is incident upon the tissue being queried and the transmitted and/or reflected light also passes into the tip **564** and returns through the optical cable assembly **530**. Light is directed via optical coupling **568** to optical filters **572**. In the fluorescence sensing modality, the optical filter **568** is a band pass or other filter that blocks the incident, excitation light while allowing the fluoresced light to pass. Filter **572** is also useful to block the emitted light from other sensing modalities and/or other light including ambient light. The filter light is coupled optically via coupling **574** to light sensors **578**. In one embodiment, light sensor **578** is an avalanche photodiode. In other embodiments, light sensor **578** is the same form as light sensors **556**. Light sensors **578** are coupled **580** with the signal processor **560** which is in tern coupled with the processor **501**. The processor **501** and signal processor **560** perform the same functions as described previously with reference to FIG. **5***a*.

FIGS. **6***a* and **6***b* show plots that are used to describe oximetry sensing modality. FIG. **6***a* shows the relationship between light absorption **601** and light wavelength **602** for a range of tissue oxygenation levels **603**. The vertical lines **620**, **624** and **628** correspond to the wavelengths of 660 nm, 790 nm and 880 nm respectively. The light absorption **601** for the range of oxygen saturation levels **603** is different for each of the wavelengths. As oxygen saturation **603** decreases, the absorption increases for red light **620** and decreases for near-infrared light **628**. At the isobestic wavelength near **624**, light absorption is invariant to oxygen saturation. This wavelength can be used for calibration and for normalization of the signal to allow for consistent readings regardless of optical density of the tissue. One embodiment of the oxygen sensing modality emits light at the isobestic wavelength, one wavelength greater than the isobestic and one wavelength less than the isobestic, and senses the absorption responsive to the measured response. Other embodiments emit one or more wavelengths of light and measure the transmitted, reflected, or otherwise measurable light to determine the absorption, slope of the absorption function, or other characteristics of the response that can be related to the blood oxygen saturation and tissue health.

FIG. **6***b* shows a plot that represents an experiment used to verify the relationship between oxygen saturation and light absorption. Red light at 660 nm represented by **652** and near infrared light at 880 nm represented by **654** are used to illuminate a section of tissue. At the time marked by **658**, blood supply to the tissue is occluded. At the time marked by **660**, the blood supply is restored. As blood supply is restricted and tissue oxygen saturation drops, the transmitted light intensity (inverse of absorption) increase for near infrared light **620** and decreases for red light **654**.

FIG. **6***c* shows a timing diagram and representative response for an algorithm according to the present invention used for oximetry-type oxygen saturation level sensing. The algorithm provides for a robust method of sensing oxygenation that results in a response that is minimally responsive to

tissue type, color, thickness, or other properties. The timing diagram in FIG. **6***c* presents the method when two wavelengths of light (red and infrared) are used. It is extendable to other numbers of sources, and other types of sources and sensors.

The diagram of FIG. **6***c* shows the output light intensity **670** and the responsive light received **672** with respect to time **674** over a time period or cycle length **676**. In one embodiment, the light emitter is a bi-color, bi-polar LED that emits red (660 nm) and infrared (880 nm) light; when a positive voltage **678** is applied, infrared light is emitted, and when a negative voltage **680** is applied, red light is emitted.

The light output intensities and corresponding response intensities are denoted with letters in the following description for use in the equations hereinbelow. In each cycle **676**, red light is emitted with intensity **678** (A) and the corresponding sensed light intensity **678** (F) is recorded. Light is then shut off **682** (B) and the corresponding received light intensity **684** (G) is recorded as a baseline. Infrared light is emitted with intensity magnitude **686** (C) and the corresponding sensed light intensity **688** (H) is recorded. To make the tissue response more invariant to tissue properties other than oxygenation (i.e. tissue optical density and thickness), the maximum intensities where light can no longer sufficiently pass through (or other transmission method) the tissue and return to the sensor. Light intensity is ramped from **686** to **682**. At time **690**, the signal is lost and the output intensity **692** (D) is recorded. Light intensity is ramped from **682** to **678**. At time **694**, the signal is regained and the output intensity **696** (E) is recorded. The times **690** and **694** and corresponding intensities **692** and **696** are determined by a simple threshold on received intensity **672**.

In another embodiment, these levels are determined by placing a threshold on a moving average, integration, derivatives, curve fitting, or other methods. Described is one embodiment of the timing for a robust oxygenation-type algorithm. Other functionally identical or similar embodiments exist.

A measure related to tissue oxygenation can be calculated responsive to the output and corresponding receiver light intensities. Initially, the "red ratio" is defined and is evaluated as (H−G)/(C−D), and the "infrared ratio" is defined and is evaluated as (F−G)/(A−E), where the letters correspond to the magnitudes of the light intensities as described. The numerator of the ratios determines the response after eliminating effects of ambient or other external light sources. The denominator of the ratios normalizes the response by the amount of light that was actually incident on the tissue that made it back to the sensor. The oxygenation is responsive to the two ratios. The "relative oxygen saturation" is defined as the red ratio divided by the infrared ratio and is related, not necessarily linearly, to the oxygen saturation of the tissue being measured. The relative oxygen saturation is useful for determining trends in oxygenation and also as a comparison with respect to time and/or a separate reference sensor. One important difference between the technique described and that of standard pulse oximetry is that the employed algorithms are not based on pulsatile flow in the tissue. Therefore, it is possible to acquire the tissue oxygen saturation even if blood flow is non-pulsatile, or even not flowing. Further, the algorithms incorporated improve measurement robustness and stability by compensating for tissue thickness and type (or more specifically, the optical impedance of the tissue being measured).

FIG. **7** is a flowchart for one inventive embodiment of the oxygen sensing modality based on oximetry. This embodiment uses oximetry-type techniques for determining the light response from tissue responsive to three excitation wavelengths. These three wavelengths can include those described earlier: one red light source, one infrared light source, and one light source at the isobestic wavelength. The measured response in the absence of an excitation light is used as a baseline intensity and subtracted from the three measured responses. All raw data is logged, and a calculation is performed to convert the light absorption for the three wavelengths to a value related to tissue oxygenation. The calculated values are compared to a database or other previously acquired or determined dataset. Although exactly three wavelengths are shown, other embodiments use one or more wavelengths of excitation light. In further embodiments, the intensities for each of the excitation lights may be ramped in intensity as detailed in FIG. **6***c* to create a more robust measurement that is invariant to tissue optical density.

FIGS. **8***a*-**8***b* show typical results for experiments with the fluorescent sensing modality. Tissue perfusion can be assessed using fluorescence. Biofluorescence can be achieved using a variety of commercially available products. One example is fluorescein isothiocyanate which is an intravenously injected, biocompatible dye which fluoresces yellow-green (peak near 520 nm) when illuminated with an blue/ultraviolet (peak near 488 nm) source. This sensing modality can be incorporated into the configurations shown to allow for multi-modality sensing, or included as a stand-alone sensor. A dense array of sensors enables imaging of the perfusion along a line and a determination if there are patches of poorly perfused tissue in an otherwise healthy region. Stapler fluorography can also utilize fluorescent microspheres and quantum dots. These entities can be used as molecular tracers to characterize tissue substructure such as vessels, or bile ducts. In addition, inflammatory mediators and other biomolecules germane to anastomosis viability can be detected though fluorography at a staple line.

FIG. **8***a* represents the measured intensity of the transmitted and/or reflected incident light **808** and the measured intensity of the fluoresced response **804** to the incident light source. The plot shows the light intensity centered at the incident and fluoresced wavelengths as fluorescent dye is instilled into or perfused though the bloodstream at time **812**. As the dye perfuses into the tissue being measured, the fluorescent response becomes evident and the sensed incident light decreases. The slope, rise time, magnitude, steady state value, shape, integral, or other characteristics and curve properties of the onset of fluorescence **816** can be used to determine characteristics of the tissue perfusion and health. The steady state values of the fluoresced light **824** and incident light **828** can be used to determine tissue perfusion and overall health and/or the type of tissue. The measured response can be used alone, with a previously collected dataset from the same or other patients, or in conjunction with a reference signal. Infusion of the fluorescent medium can be introduced either in a single injection, or it can be ramped up in either continuously or in discrete increments. By varying the amount of fluorescent medium introduced into the patient, continuous or multiple measurements can be performed of the characteristics of the onset of fluorescent response.

FIG. **8***b* shows typical results for passing a fluorescence sensing probe **850** across a tissue sample **852**. In one case, the fluoresced response **858** serves as a baseline for healthy tissue **856** and the decreased intensity **862** corresponds to a region of tissue that is depleted of blood supply **860**. Alternately, the baseline intensity can be the lower level **862** and the fluorescence peaks to **858** as the probe passes over a blood vessel **860**. This scanning technique can be used to determine sections of tissue with proper perfusion. In one embodiment,

multiple sensor probes **850** are integrated in a linear, grid like, or other arrangement on the surface of a surgical instrument such as a stapler, a retractor, a grasper, a clip applier, a probe, a scope, a needle, a catheter, a mesh substrate, or other device.

FIG. **9** is a flowchart for one embodiment of the inventive fluorescence sensing modality. Light containing or centered at a wavelength that excites the fluorescent medium is transmitted into the tissue. The light intensity of the fluorescent response is then measured; optical filters, wavelength selective light receivers, or a spectrometer are used to differentiate excitation light and fluorescent response. The measured response in the absence of an excitation light is used as a baseline intensity and subtracted from the fluorescent response. All raw data is logged, and a calculation is performed to determine one or more properties of the onset of the fluorescent response and the steady state value as described earlier. The calculated values are compared to a database or other previously acquired or determined dataset. This sensing modality can be combined with that described by the flowchart of FIG. **7**. In one embodiment, both oximetry-type sensing as represented in FIG. **6** and FIG. **7** and fluorescence-type sensing as represented in FIG. **8** and FIG. **9** are combined into a single integrated device. The schematic diagram shown in FIG. **5** shows how light sources and detectors for both sensing modalities can be integrated into a single system. Other sensing modalities, optical or other types, can be combined to perform multi-modality sensing on the working surface of surgical instruments.

FIGS. **10***a*-**10***c* present techniques that can be used to perform said oximetry-type and/or fluorescence-type sensing. These techniques can be combined with other sensing modalities including optical sensors, electrical sensors, chemical sensors, mechanical sensors, MEMS sensors, nano sensors, biochemical sensors, acoustic sensors, immunologic sensors, fluidic sensors, or other types of sensors.

FIG. **10***a* shows a surgical stapler embodiment of the system configuration where all light sources and detectors are located external of the surgical instrument's body. In this embodiment, the light sources and detectors are located in control unit **1001** and sensing, control, calculations, and communications are performed in control electronics **1003**. In one embodiment, control unit **1001** constitutes durable equipment and instrument **1028** is a potentially disposable device. For each measurement point, one or more light sources **1005** are coupled optically via **1007** to a light combiner **1009**. The light sources can be narrowband emitters such as LEDs and lasers and/or broadband light sources such as white lights and can be use with or without additional optical filtering. For the same measurement point, one or more light receivers **1001** are coupled optically via **1013**. The light receivers can be photodiodes, photodiode arrays, avalanche photodiodes, photomultiplier tubes, linear and two dimensional CCDs, CMOS sensors, spectrometers, or other sensor types. The light traveling through couplers **1009** and receiver couplings **1013** are coupled to an optical connector **1020**. In one embodiment, this connector is a standard high density fiber optic connection and coupling **1022** is a standard high density fiber optic cable. Coupling **1022** connects to the sensing instrument **1028** at connector **1024** and passes through fiber **1030** to a breakout **1032**. Sensor points **1034** can be either single fibers or multi-fiber sensor tips as represented in FIGS. **4***a-e*. The sensor tips transmit the incident light onto tissue **1036** and/or receive the reflected, transmitted, and/or fluoresced light from said tissue.

FIG. **10***b* depicts an embodiment where the light emitting and receiving components are located onboard a surgical instrument. In this embodiment, circuit board **1051** is mounted in or on the instrument and coupled via **1053** to a control unit. Coupling **1053** is electrical, optical or wireless. Attached to circuit board **1051** are light sources **1057** and light receivers **1060**. In one embodiment, they are standard surface mount LEDs and photodiodes. Light guides, light combiners, and/or light splitters **1064** direct light to and from the sensing working surface **1066** of the instrument to and from the tissue being monitored **1068**. In one embodiment, **1051** represents a flexible medium and light sources and receivers **1057** and **1060** represent alternative light sources and emitters such as organic LEDs and organic photo detectors.

FIG. **10***c* shows a further embodiment where the light emitting and receiving components are located onboard a surgical instrument. In this embodiment, the electronics are microfabricated into a compact sensing element that can fit onto the working surface of the instrument. As described hereinabove, coupling **1083** connects the circuit to an external controller. The circuit is built on base **1081**. Light emitters **1087** and detectors **1090** are embedded in layer **1092**. Coupled to the light sources and detectors are micro fabricated light guides, light combiners, and/or light splitters **1094** in layer **1096**. The light guides direct light to and from the tissue being monitored **1098**.

FIGS. **11***a*-**11***c* depict further embodiments of sensing surgical instruments and devices according to the present invention. FIG. **11***a* shows a sensing flexible mesh **1104** that contains sensing elements **1106**. Sensing elements **1106** can be electrical, optical, chemical, or other sensor types used to monitor the tissue **1102** or other operational parameters. The mesh **1104** can mold to the surface of tissue **1102**. In one embodiment, sensors **1106** are oxygenation sensors as described previously and are used to monitor the tissue health and other tissue properties. In addition, when there is a plethora of sensors, mapping of the oxygenation levels of the surface of the tissue **1102** can be performed. If the location of the sensors is known with respect to the tissue or imaging device, then this mapping can be overlaid on medical imaging information including x-ray, computed tomography, magnetic resonance imaging or ultrasound images and volumes, or it can be overlaid on a video signal from an endoscope or other camera. In another embodiment, sensors **1104** are electrical sensors that are used for EMG or other electrical activity or impedance mapping. The mesh is coupled via **1108**. Coupling **1108** is electrical, optical, or wireless. Sensors **1104**, in optical sensing modalities, are either onboard electronics or the distal tips of optically coupled emitters and detectors.

The sensing surgical mesh can be generally described as a rigid or flexible surface that contains sensing elements. The sensing elements detect information about the tissue upon which they are placed. The mesh is flexible, or preshaped to conform to the tissue being monitored. In one embodiment wherein the mesh is bioabsorbable, the mesh is made of bioabsorbable polymers similar to those used in conventional absorbable sutures. In another embodiment wherein the mesh is durable, the mesh is made of polymers similar to those used in conventional non-absorbable sutures. In a further embodiment, the substrate is an adhesion barrier material, such as Seprafilm®, available from Genzyme Corp. of Cambridge, Mass. The tissue being monitored is either internal tissue, such as an organ being monitored after transplant or a bowel segment whose perfusion is to be verified, or is external tissue, such as a skin flap being monitored for reconstructive surgery, or skin being monitored for the prevention of bed sores. The mesh sensor array is either a temporary device used

during a procedure (either single use or reusable), permanently implantable, or of a bio degradable, bio absorbable nature as is known in the art.

FIG. **11***b* shows a surgical retractor **1122**. The working surface of the retractor **1124** is instrumented with sensors as previously described (i.e., with sensing elements **1106**) for measuring properties of a tissue **1128**. In addition to monitoring tissue properties, interactions with tissue **1128** are measured using strain gages, piezoelectric sensors, load cells, multi-axis force/torque sensors, and/or other sensors **1130** and **1132**. The retractor handle **1134** is held manually by a member of the operating room staff, mounted to a frame or passive arm, or held by a robotic retraction system. Coupling **1136** couples sensors **1126**, **1120**, and/or **1132** to an onboard or external control interface (not shown) as described hereinabove. In one embodiment, sensors **1126** are oximetry-type sensors comprising of a plethora of multi-color LEDs and photodiodes and sensors **1130** and **1132** are either strain gages or multi-axis force/torque sensors respectively for measuring the forces incident upon the tissue during retraction while simultaneously monitoring oxygenation levels. In the case of a robotic retraction system or other robotic-assisted surgery scenario, the sensed information including interaction forces and tissue status is used to close the control loop for the robot and/or provide warnings or augment the motions of the robot manipulator.

FIG. **11***c* displays a surgical grasper that is instrumented with sensors **1144** mounted on grasper jaws **1146** and **1148**. The grasper clamps or otherwise contacts tissue **1142** and senses oxygenation, tissue perfusion, electrical properties, chemical properties, temperature, interaction forces, grasping forces, and/or other parameters. Coupling **1152** couples sensors **1144** to an onboard or external control interface (not shown) as described hereinabove. Sensors **1144** can be placed on one or both sides of the jaw and/or on the shaft **1150** of the instrument. In one embodiment, the grasper measures the oxygenation level of the tissue being grasped while simultaneously monitoring grasping force and other tissue interaction forces.

FIG. **11***d* shows a configuration for a sensor implanted in the body that relays information back to a controller. Sensor device **1160** contains one or more sensing elements **1162**. The sensing elements can be any of the type described earlier including oxygenation, fluorescence, tissue perfusion, general health, tissue electrical impedance, tissue electrical activity, interaction forces, pH, electromyography, temperature, spectroscopy, fluid flow rate, fluid flow volume, pressure, biomarkers, radiotracers, immunologic, chemical, nerve activity, and evoked potential, and other sensor types capable of determining characteristics of tissue. The sensor device **1160** is placed inside of, on the surface of, embedded into, or wrapped around tissue **1164**. The tissue being monitored is, for example, an organ, a bowel segment, a blood vessel, a chest wall, or other biological tissue. The sensor can be temporary, permanently implantable, or bioabsorbable/biodegradable inside of body **1166**. In one embodiment, the sensor device is implanted onto the bowel and used for monitoring the tissue after a procedure and for obtaining data related to short and long term outcomes. In another embodiment, the sensor is a ring that is placed around a blood vessel and is used to monitor blood flow in said vessel.

In some embodiments, one or more sensor devices on one or more tissues **1164** are communicatively coupled via **1170** to a communications interface **1172**. In one embodiment, the coupling **1170** is a wireless link where the power from a radio frequency signal generated by **1172** powers the sensor device **1160** which then takes a measurement and return data via wireless coupling **1170**. The communication interface is coupled via **1174** to a main control unit **1176**. In another embodiment, the communications interface **1172** is a portable battery powered device that can be carried by the patient, or a fixed device placed inside or outside of a hospital or a medical professional's office for powering and monitoring the internal sensors **1160**. The communication interface **1172** can conveniently obtain acute, short, and long term follow-up data about a procedure after the surgery is complete. The communications interface **1172** and controller **1176** may be one in the same. In one embodiment, the controller **1176** is the main system's base control unit **120**. In another embodiment, the communication interface **1172** is directly in communication with the main system's base unit **120** or the central database **131** directly.

In a further embodiment of the system shown in FIG. **11***d*, the sensor device contains a MEMS sensing element and communications electronics, is placed in or on internal tissue, and communicates wirelessly with and receives power from an external radio frequency source for the purpose of post procedure patent monitoring. In another embodiment, the sensing element is made of biocompatible materials known in the art, and an attached antenna is bioabsorbable in the patient's body. The associated electronics and/or antenna can be made either bioabsorbable or biodegradable, or such that their presence does not have any significant effect on the patient, or any combination thereof.

FIG. **11***e* shows a detailed view of an embodiment of sensor unit **1160**. The sensor unit is built into substrate **1180** which, in one embodiment, is composed of a bioabsorbable polymer as is known in the art. The sensor unit contains a communications device **1182** which is coupled to an antenna **1184**. In certain embodiments, the antenna body is made of a fully or partially bioabsorbable/biodegradable polymer, and contains connected tubes that are filled with conductive and biocompatible gel or liquid. The communications device is biocompatible, and can be bioabsorbable. Coupled via **1188** to the communications device **1182** are one or more sensing elements **1186**. The sensing elements can be of any of the type described earlier. In one embodiment, the sensing elements are fully or partially bioabsorbable/biodegradable. In certain embodiments, the sensing elements and communications device obtain electrical power remotely from a radio frequency source, such as in RFID technology as known in the art, and use this power to perform sensing operations and to transmit data to communications interface **1172**. The embodiment shown in FIG. **11***e* is a representative configuration of the sensor unit; other types, shapes, and configurations are understood to be included as well.

In further embodiments of the present invention, an absorbable optical fiber (such as shown in FIGS. **4***a-e*) comprises at least a core and an outer cladding made out of bioabsorbable materials. Its layers can be made out of bioabsorbable materials with different time constants for degradation. For example, the cladding is thin but of a material composition that degrades very slowly, and the core is of a composition that degrades very fast since once the cladding is degraded, the fiber is useless. This bioabsorbable optical fiber is used for the light guides for optical sensors and/or for a communicative coupling between the sensors and a controller.

FIGS. **12***a-c* shows a surgical staple or clip with integrated sensing capabilities. The staple, clip, suture, or other fastener itself can be used as an electrode, as a strain or force sensor, or as an optical pathway. Forces pulling on an anastomosis or other tissue joining can cause failure. By placing force measuring instrumentation on either a stapler or other instrument's working surface, or on staples, clips, sutures, or other

fasteners themselves, it is possible to measure the strain induced on the tissue being joined.

FIG. **12***a* shows a staple with embedded sensors. The staple can include any of the sensing modalities discussed earlier. In one embodiment, strain sensing for measuring the pulling or pushing forces exerted by tissue on the staple legs **1206** may be incorporated into the fastener. In another embodiment, strain gages **1204** are fabricated on the surface of the staple as **1204**. In yet another embodiment, a coating or partial layer of a piezoelectric or resistive coating **1224** is fabricated around staple core **1222** as shown in cross-section A-A in FIG. **12***b*. In other embodiments, the staple is a hollow tube **1224** whose inner core **1222** is made of a piezoelectric, resistive, or other material or component that permits measurement or bending load on the staple legs **1206**. This design is extendable to incorporating sensing capabilities into any surgical fastener including staples, clips, and sutures. The staple, clip, or other fastener is made of in whole or in part of bioabsorbable/biodegradable, biocompatible materials as known in the art.

FIGS. **13***a-b* depict embodiments where a staple, clip, or other electrode is used for electrical sensing on the surface of a surgical instrument. FIG. **13***a* shows an embodiment where the instrument is used for tissue electrical impedance sensing. The electrical resistance/impedance of the tissue can be used to indicate tissue properties. By measuring electrical impedance of internal tissue at the surface of a surgical instrument, it is possible to determine the tissue's status including indications of hypoxia and ischemia. Electrodes or electrical contacts placed into the tissue are used as measurement points, the impedance measured between adjacent points and across any combination thereof. These electrodes are placed as small tips (invasive or surface contact only) on the working surface of a surgical instrument.

The instrument surface **1302** contains one or more staples, clips, or other electrodes **1304** that act as electrical contacts. The electrical contacts **1304** come in contact with tissue **1308** either on the surface or by penetrating into the tissue. The electrical impedance or resistance between the electrical contacts (either on the same staple or clip, or between adjacent or other pairs) is represented by **1310**. Contacts are connected via coupling **1312** to a controller **1314** where the measurement electronics are housed. Coupling **1312** is either electrical, optical, or wireless. Additional surfaces, instruments, or opposing stapler or grasper jaws **1320** contain additional electrodes **1322**. They are coupled via **1324** to an interface **1326** and further coupled via **1328** to the same or a different controller **1314**, or coupled directly to the controller **1314**.

FIG. **13***b* shows an embodiment where the instrument is used for tissue electrical activity sensing, including nerve and muscle stimulation and sensing. Electrical activity in tissue can be used to assess the tissue's viability. The muscular and neuronal activity that occurs in the tissue of interest is measured using techniques similar to those in electromyography: either the naturally occurring activity, or the response to an excitation due to an electrical or other impulse. Implanting electrodes into the working surface of a surgical instrument enables the viability of the local tissue to be quantified.

The instrument surface **1342** contains one or more staples, clips, or other electrodes **1344** that act as electrical contacts. The electrical contacts **1344** come in contact with tissue **1346** either on its surface or by penetrating into the tissue. The contacts are coupled via **1348** to a controller **1350** where the measurement electronics are housed. Coupling **1350** is either electrical, optical, or wireless. Additional surfaces, instruments, or opposing stapler or grasper jaws **1352** contain additional electrodes **1354**. They are coupled via coupler **1356** to an interface **1358** and further coupled by coupler **1360** to the same or a different controller **1350**, or coupled directly to the controller **1314**. The electrical contacts can be used for both sensing and/or stimulation of the tissue or components thereof. A separate electrical contact **1362** is placed in tissue **1346**. The separate contact can serve as a reference or as a source of nerve, muscle, or other stimulation that is sensed by the other electrical contacts **1344** and **1354**. Reference contact **1362** is coupled via coupler **1364** to the controller **1350**.

FIG. **14** shows a schematic layout of an integrated expert system according to the present invention. The base unit **1401** contains all processing, sensing, control, signal processing, communication, storage, and other required components. Coupled via coupler **1403** is sensing surgical instrument(s) **1405**. These instruments include, but are not limited to, all of the instruments and embodiments described hereinabove. Sensing modalities include, but are not limited to, any of those described herein, including oxygenation including oximetry-type sensing, fluorescence, tissue perfusion, general health, tissue electrical impedance, tissue electrical activity, interaction forces, pH, electromyography, temperature, spectroscopy, fluid flow rate including laser or ultrasound Doppler measurement, fluid flow volume, pressure, levels of biomolecules and electrolytes, biomarkers, radiotracers, immunologic, chemical, nerve activity, evoked potential, and other sensor types capable of determining characteristics of tissue. Coupling **1403** is electrical, optical, and/or wireless. Instruments **1405** are tethered via electrical or optical cables, have built in wireless functionality, or have a reusable battery powered wireless pack that powers the instrument's sensors and/or the instrument itself, and/or couples the signals to the base unit **1401**. A reference measurement sensor **1415** of the same type as said surgical instruments and coupled via coupler **1413** to base unit **1401** is used to obtain patient-specific reference measurements used to help determine tissue health and predict procedural outcomes. In addition to the instruments, a robotic manipulator useable to control the instruments and or reference sensor is coupled to the base unit **1401**. The manipulator can be controlled in a closed loop fashion to optimize procedural outcomes responsive to real-time and prior patient specific information and prior statistical and other data.

Patient status sensing including cameras, infrared imaging, thermal imaging, spectroscopic imaging, and other sources **1425** and operating room monitors **1435** including anesthesia equipment monitors and vital signs monitors which include, but are not limited to, pulse rate and quality measurement, respiration rate and quality measurement, blood pressure measurement, blood gas analysis, pulse oximetry, and ECG, feed into base unit **1401** via couplings **1423** and **1433** respectively. This systemic data is recorded and synchronized with that of the sensing instruments, and also aids in determining tissue health and in predicting procedural outcomes. The system can also be coupled via coupling **1443** to the hospital's patient data storage system **1445** so that collected data is included in the database of patient medical history information. Further, patient medical history is incorporated into the system's analysis of sensor data to better predict and optimize outcomes.

All relevant data collected and post-procedural outcomes are stored in a central repository **1455** that is used to generate a statistical model that allows prediction of outcomes based on current sensor data. The coupling **1453** is bi-directional; prior data is used for analysis of the current procedure and current patient data and outcomes are added to the database **1455** for future use. Coupling **1453** need not be a permanent

connection; data in a local copy of **1455** can be retrieved from and updated on each base unit **1401** at regular service intervals.

The collected data, statistical model, predicted outcomes, and other relevant information is presented in a comprehensible manner to the surgeon or other operating room staff using one or more output devices **1462** coupled to base unit **1401** via coupling **1460**. Coupling **1460** is wired or wireless, or output device **1462** can be integrated directly into the control unit **1401**. Presentation of results can be performed in numerous ways including, but not limited to: visual feedback, audio feedback, force or other haptic feedback, or other forms of sensory substitution. The feedback can include plots, text-based messages, verbal messages, audible warnings, video overlays, and feedback on a robotic manipulator. Communication with an external database or other source of data is achieved with a communication device **1468** communicatively coupled to the base unit **1401** via **1466**. The coupling can be wired, wireless, or the communications device may be embedded in the base unit. Communications device **1468** can be a conventional modem, or an internet or other network connection.

The present invention can be practiced by employing conventional materials, methodology and equipment. Accordingly, the details of such materials, equipment and methodology are not set forth herein in detail. In the previous descriptions, numerous specific details are set forth, such as specific materials, structures, chemicals, processes, etc., in order to provide a thorough understanding of the present invention. However, it should be recognized that the present invention can be practiced without resorting to the details specifically set forth. In other instances, well known processing structures have not been described in detail, in order not to unnecessarily obscure the present invention.

Only an exemplary embodiment of the present invention and but a few examples of its versatility are shown and described in the present disclosure. It is to be understood that the present invention is capable of use in various other combinations and environments and is capable of changes or modifications within the scope of the inventive concept as expressed herein.

What is claimed is:

1. A system comprising:

a surgical instrument having a sensor configured to generate a signal indicative of a property of a subject tissue of a patient;

a signal processor configured to receive the signal and convert the signal into a current dataset;

a memory configured to store the current dataset; and

a processor configured to determine a relationship between the current dataset and datasets of signals indicative of the property of a subject tissue of other patients previously stored in the memory, to determine a weighting factor based on the determined relationship between the current dataset and the previously stored datasets, and to interpolate or extrapolate a physical condition of the subject tissue or guide a current procedure being performed on the subject tissue based on the determined weighting factor and outcomes of the other patients previously stored in the memory,

wherein the processor is further configured to predict the likelihood of success of the current procedure being performed on the subject tissue based on the weighting factor and the outcomes of the other patients previously stored in the memory.

2. The system of claim **1**, further comprising a recorder configured to record the signal from the sensor and the current dataset into the memory.

3. The system of claim **1**, wherein the memory is operative to store data relating to at least one of pre-procedure data, during-procedure data, post-procedure data, immediate outcomes, short-term outcomes, and long-term outcomes of previous instances of the procedure, and the processor is further configured to predict the likelihood of success of the current procedure responsive to the data relating to the outcomes.

4. The system of claim **3**, wherein the processor is further configured to add at least one of pre-procedure data, during-procedure data, post-procedure data, and immediate outcomes of the current procedure to the memory.

5. The system of claim **3**, wherein the processor is further configured to add short-term and long-term outcomes of the current procedure to the memory.

6. The system of claim **3**, further comprising patient monitoring equipment configured to generate patient condition data and transfer the patient condition data to the processor, wherein the processor is configured to assess the tissue condition and predict the likelihood of success of the current procedure responsive to the patient condition data.

7. The system of claim **6**, wherein the patient monitoring equipment is configured to perform at least one of systemic monitoring, local monitoring, extracorporeal monitoring, intracorporeal monitoring, invasive monitoring and noninvasive monitoring.

8. The system of claim **6**, wherein the patient monitoring equipment includes at least one of a vital sign monitor and anesthesia equipment.

9. The system of claim **6**, wherein the patient monitoring equipment comprises a sensor consisting essentially of a rigid or flexible substrate and a plurality of sensing elements mounted to the substrate and configured to monitor a property of a biological tissue of a patient.

10. The system of claim **6**, wherein the patient monitoring equipment comprises at least one of an implantable sensor and a marker introduced to the subject tissue, the monitoring equipment remaining at the subject tissue after the current procedure and configured to generate the patient condition data.

11. The system of claim **3**, further comprising patient status sensing equipment configured to generate patient status data and transfer the patient status data to the processor, wherein the processor is configured to assess the tissue condition, guide the current procedure, or predict the likelihood of success of the current procedure responsive to the patient status data.

12. The system of claim **11**, wherein the patient status sensing equipment comprises at least one of thermal imaging equipment, a camera, and spectroscopic imaging equipment.

13. The system of claim **1**, further comprising a communications device configured to communicate with a remote database comprising previously stored datasets and data relating to outcomes of previous instances of the procedure;

wherein the processor is configured to compare the current dataset with the datasets and data of the remote database.

14. The system of claim **13**, wherein the processor is further configured to update the remote database using the current dataset and at least one of pre-procedure data, during-procedure data, post-procedure data, immediate outcomes, short-term outcomes, and long-term outcomes of the current procedure.

15. The system of claim 1, further comprising a communications device configured to communicate with a patient data store comprising a medical history of the patient undergoing the current procedure;

wherein the processor is configured to predict the likelihood of success of the current procedure responsive to the medical history of the patient.

16. The system of claim 15, wherein the processor is further configured to update the medical history of the patient using the current dataset and the outcome of the current procedure.

17. The system of claim 1, wherein the surgical instrument includes at least one of a surgical stapler, a clip applier, a grasper, a retractor, a scalpel, a forceps, a laparoscopic tool, an open surgical tool, a cauterizing tool, a robotic tool, a scissors, a clamp, a needle, a catheter and a trochar.

18. The system of claim 1, further comprising a reference measurement instrument having a sensor configured to measure a reference tissue and generate a reference measurement signal.

19. The system of claim 18, wherein the reference tissue is a tissue of the patient.

20. The system of claim 19, wherein the sensor associated with the surgical instrument and the sensor associated with the reference measurement instrument are configured to measure at least one of oxygenation, fluorescence, tissue perfusion, general health, tissue electrical impedance, tissue electrical activity, interaction force, pH, electromyography, temperature, spectroscopy, fluid flow rate, fluid flow volume, pressure, biomarkers, radiotracers, immunologic characteristics, biochemical characteristics, nerve activity, and evoked potential.

21. The system of claim 18, wherein the signal processor is configured to convert the reference measurement signal to a reference baseline measurement dataset, and the processor is configured to assess the physical condition of the subject tissue responsive to the reference baseline measurement dataset.

22. The system of claim 18, wherein the reference measurement instrument is configured to grasp the reference tissue.

23. The system of claim 18, further comprising a robotic manipulator configured to control the reference measurement instrument.

24. The system of claim 1, wherein the sensor comprises one of an optical sensor, a chemical sensor, mechanical sensor, a MEMS device, a nano sensor, an acoustic sensor, a fluid sensor and an electrical sensor.

25. The system of claim 1, further comprising a robotic manipulator configured to control the surgical instrument.

26. The system of claim 1, wherein the sensor is configured to generate signals before, during and after actuation of the surgical instrument, and the signal processor is configured to process such signals and include such signals in the dataset.

27. The system of claim 1, further comprising an attaching device removably mountable to the surgical instrument and configured to hold the sensor and configured to position the sensor relative to the surgical instrument.

28. The system of claim 27, wherein the attaching device comprises at least one of a shell, a sleeve, and a clip.

29. The system of claim 27, wherein the surgical instrument comprises a stapler.

30. A system comprising:

a particular synthetic light re-emitting medium adapted to be introduced into a subject tissue of a patient; and

a surgical instrument configured to manipulate biological tissue comprising:

an incident light source configured to illuminate the subject tissue into which the particular light re-emitting medium has been introduced;

a light sensor configured to receive an optical response from the light re-emitting medium introduced into the subject tissue and to generate a signal indicative of the optical response; and

a processor configured to receive the signal and to determine a physiologic tissue characteristic of the subject tissue responsive to the optical response as indicated by the signal and based on the particular light re-emitting medium introduced into the tissue,

wherein the processor is further configured to use the determined physiologic tissue characteristic to further guide a surgical procedure.

31. The system of claim 30, wherein the processor is configured to determine the physiologic tissue characteristic responsive to a slope, rise time, magnitude, steady state value, shape, integral or other curve property of the optical response.

32. The system of claim 30, wherein the processor is further configured to determine the physiologic tissue characteristic based on steady-state values of the optical response.

33. The system of claim 32, wherein the physiologic tissue characteristic of the subject tissue is a perfusion of the tissue.

34. The system of claim 30, comprising an array of the sensors disposed on a surface of the surgical instrument.

35. The system of claim 34, wherein the surgical instrument comprises one of a stapler, a retractor, a grasper, a clip applier, a probe, a scope, a needle, a catheter and a mesh substrate.

36. The system of claim 30, wherein the light re-emitting medium is configured to be injected into the tissue.

37. The system of claim 30, wherein the system is configured to wirelessly communicate the signal generated by the light sensor to the processor.

38. A sensing device comprising a rigid or flexible substrate and a plurality of sensing elements mounted to the substrate for monitoring a property of a biological tissue of a patient,

wherein the sensing elements are communicatively connected to a processor configured to use a signal acquired by the sensing elements to determine a weighting factor based on a relationship between the acquired signal and datasets of signals indicative of the property of a biological tissue of other patients previously stored in a memory, to provide information to further guide a surgical procedure based on the property, and to predict the likelihood of success of the surgical procedure based on the determined weighting factor and outcomes of the other patients previously stored in the memory.

39. The sensing device of claim 38, wherein the substrate is substantially conformable to the shape of the biological tissue of a patient.

40. The sensing device of claim 38, wherein the substrate is a flexible mesh.

41. The sensing device of claim 38, wherein the sensing elements are configured to measure oxygenation of the tissue.

42. The sensing device of claim 38, wherein the sensing elements are arranged on the substrate and configured to map the property of the biological tissue of a patient.

43. The sensing device of claim 38, wherein the sensing elements are configured to measure electrical activity of the biological tissue of a patient, and are arranged for mapping the electrical activity of the biological tissue of a patient.

44. The sensing device of claim 38, wherein the sensing elements are configured to measure the optical response of a light re-emitting medium introduced into a subject tissue, and

are arranged for mapping the optical response of the light re-emitting medium introduced into a subject tissue, on the surface of the biological tissue of a patient.

45. A surgical fastener comprising a sensor configured to measure mechanical or physiologic properties of a biological tissue of a patient, said sensor being in contact with the surgical fastener,

wherein:

said fastener is an implantable fastener configured to hold tissue together, and

said sensor is configured to obtain measurement results corresponding with mechanical or physiologic properties of the biological tissue of a patient.

46. The surgical fastener of claim **45**, comprising one of a staple, a suture or a clip.

47. The surgical fastener of claim **45**, comprising a plurality of strain sensors located at corners or on the sides of a staple on an outer surface of the staple.

48. The surgical fastener of claim **45**, wherein the sensor comprises a sensing coating around a circumference of a staple.

49. The surgical fastener of claim **48**, wherein the sensor comprises at least one of a piezoelectric coating and a resistive coating.

50. The surgical fastener of claim **45** comprising a staple, wherein the staple is hollow and a strain sensor is disposed inside the staple and configured to measure a bending load on a leg of the staple.

51. The surgical fastening device of claim **45**, wherein the sensor comprises at least one of an electrode and a MEMS sensor, and the surgical fastener comprises a remotely powered radio frequency transmitter unit.

52. The surgical fastener of claim **45**, wherein the fastener is an implantable fastener configured to substantially permanently hold the tissue together.

53. A system comprising:

a surgical instrument configured to manipulate biological tissue having a sensor configured to generate a signal indicative of a property of a subject tissue of a patient;

a reference measurement instrument having a sensor configured to measure a reference tissue and generate a reference measurement signal,

wherein the surgical instrument and the reference measurement instrument are physically distinct instruments that are configured to be separately mounted on the subject tissue and the reference tissue;

a signal processor configured to receive the signal and convert the signal into a current dataset, and configured to receive the reference measurement signal and convert it into a current reference dataset;

a memory configured to store the current dataset and the current reference dataset; and

a processor configured to compare the current dataset with the current reference dataset, and to assess a physical condition of the subject tissue and guide a current procedure being performed on the tissue, responsive to the comparison,

wherein the reference tissue is a tissue of the patient, and

wherein the signal processor is configured to convert the reference measurement signal to a reference baseline measurement dataset, and the processor is configured to assess the physical condition of the subject tissue responsive to the reference baseline measurement dataset.

54. The system of claim **53**, wherein the reference measurement instrument is configured to grasp the reference tissue, and

comprises a sensor.

55. The system of claim **53**, wherein the reference measurement instrument sensor comprises one of an optical sensor, a chemical sensor, mechanical sensor, a MEMS device, a nano sensor, an acoustic sensor, a fluid sensor and an electrical sensor.

56. The system of claim **53**, wherein the reference measurement instrument sensor is configured to measure at least one of oxygenation, fluorescence, tissue perfusion, general health, tissue electrical impedance, tissue electrical activity, interaction force, pH, electromyography, temperature, spectroscopy, fluid flow rate, fluid flow volume, pressure, biomarkers, radiotracers, immunologic characteristics, biochemical characteristics, nerve activity, and evoked potential.

57. The system of claim **53**, further comprising a robotic manipulator configured to control the reference measurement instrument.

58. The system of claim **53**, wherein the system is configured to wirelessly communicate at least one of the signal generated by the sensor of the surgical instrument and the reference measurement signal generated by the sensor of the reference measurement instrument to the signal processor.

59. A system for monitoring a biological tissue of a patient's body, comprising:

a sensor implantable in the patient's body configured to generate a signal indicative of a property of the biological tissue;

a controller configured to receive the signal outside the patient's body; and

a communications interface configured to communicate the signal from the sensor to the controller, wherein:

the sensor is configured to place in, on, in contact with, embedded into, or surrounding the biological tissue,

the sensor is fully or partially bioabsorbable or biodegradable in the patient's body, and

the communications interface is wireless, and the sensor is configured to wirelessly communicate the signal to the communications interface.

60. The system of claim **59**, wherein the sensor is powered externally from a radio frequency source.

61. The system of claim **59**, wherein the sensor is configured to monitor the biological tissue property before, during or after a procedure performed on the patient.

62. The system of claim **61**, wherein the sensor is configured to monitor short and long-term outcomes of the procedure.

63. The system of claim **59**, wherein the communications interface is portable.

64. The system of claim **63**, wherein the communications interface is configured to use a radio frequency source to power the sensor.

65. The system of claim **59**, wherein the sensor comprises an antenna, and at least one of the communications interface and the antenna is fully or partially bioabsorbable or biodegradable in the patient's body.

66. The system of claim **59**, wherein the sensor comprises a bioabsorbable or biodegradable optical fiber.

67. The system of claim **66**, wherein the optical fiber has a core and an outer cladding comprising bioabsorbable or biodegradable materials, and the cladding material degrades substantially more slowly relative to the core material.

68. A sensing device comprising an attaching device removably mountable to a surgical instrument, and a plurality of sensing elements mounted to the attaching device for monitoring a property of a subject tissue,

wherein said plurality of sensing elements are arranged to be directed to a working surface of the surgical instrument, and

wherein the sensing elements are communicatively connected to a processor configured to use a signal acquired by the sensing elements to determine a weighting factor based on a relationship between the acquired signal and datasets of signals indicative of the property of a biological tissue of other patients previously stored in a memory, to provide information to further guide a surgical procedure based on the property, and to predict the likelihood of success of the surgical procedure based on the determined weighting factor and outcomes of the other patients previously stored in the memory.

69. The sensing device of claim **68**, wherein the attaching device comprises at least one of a shell, a sleeve, and a clip.

70. The sensing device of claim **69**, wherein the sensing device is single-use and disposable.

71. The sensing device of claim **69**, wherein the attaching device is configured to be removably mountable to a surgical stapler.

72. The sensing device of claim **71**, wherein the sensing elements are arranged along a working surface of the surgical stapler.

73. The sensing device of claim **69**, wherein the attaching device is removably mountable to the surgical instrument without impairing the functionality of the surgical instrument.

74. The sensing device of claim **68**, wherein the sensing elements is configured to measure at least one of oxygenation, fluorescence, tissue perfusion, general health, tissue electrical impedance, tissue electrical activity, interaction force, pH, electromyography, temperature, spectroscopy, fluid flow rate, fluid flow volume, pressure, biomarkers, radiotracers, immunologic characteristics, biochemical characteristics, nerve activity, and evoked potential.

75. The sensing device of claim **74**, wherein the processor is further configured to assess subject tissue viability based on the monitored property.

76. The sensing device of claim **74**, wherein the sensing device further comprises an output configured to provide the information to guide a procedure.

77. The sensing device of claim **76**, further comprising a reference measurement sensor configured to measure a reference tissue and generate a reference measurement signal.

78. The sensing device of claim **77**, wherein the reference signal is configured to aid in assessing subject tissue viability.

79. An apparatus comprising an accessory for attachment to a surgical instrument, the accessory including a plurality of sensing elements,

wherein said plurality of sensing elements are arranged to be directed to a working surface of the surgical instrument, and

wherein the sensing elements are communicatively connected to a processor configured to use a signal acquired by the sensing elements to determine a weighting factor based on a relationship between the acquired signal and datasets of signals indicative of a property of a biological tissue of other patients previously stored in a memory, to provide information to further guide a surgical procedure based on the property, and to predict the likelihood of success of the surgical procedure based on the determined weighting factor and outcomes of the other patients previously stored in the memory.

80. The apparatus of claim **79**, wherein the sensing elements are configured to measure at least one of oxygenation, fluorescence, tissue perfusion, general health, tissue electrical impedance, tissue electrical activity, interaction force, pH, electromyography, temperature, spectroscopy, fluid flow rate, fluid flow volume, pressure, biomarkers, radiotracers, immunologic characteristics, biochemical characteristics, nerve activity, and evoked potential.

81. The apparatus of claim **79**, wherein the accessory is configured to replace an element of a standard surgical instrument.

82. The apparatus of claim **81**, wherein the surgical instrument is a surgical stapler.

83. The apparatus of claim **82**, wherein the element of the surgical instrument is an anvil.

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专利名称(译)	具有用于检测组织特性的传感器的手术器械和使用这种器械的系统		
公开(公告)号	US9204830	公开(公告)日	2015-12-08
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申请(专利权)人(译)	赞德JASON MATTHEW FISCHER GREGORY SCOTT		
当前申请(专利权)人(译)	SURGISENSE CORPORATION		
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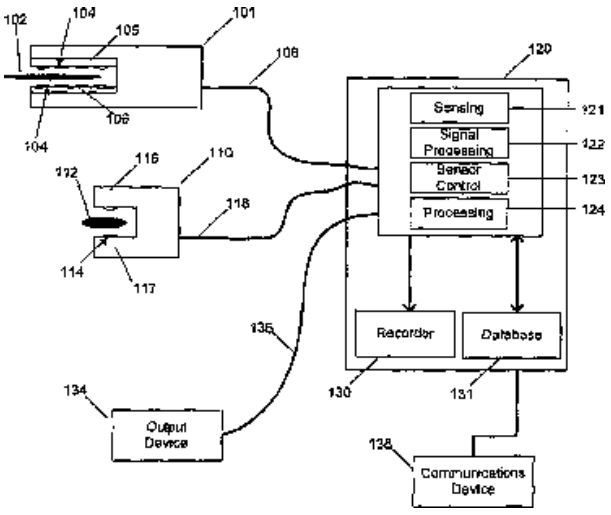
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