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

CHIRURGISCHE INSTRUMENTE MIT SENSOREN ZUR ERKENNUNG VON GEWEBEEIGENSCHAFTEN SOWIE SYSTEME ZUR VERWENDUNG SOLCHER INSTRUMENTE

INSTRUMENTS CHIRURGICAUX DOTES DE CAPTEURS DESTINES A DETECTER DES PROPRIETES TISSULAIRES ET SYSTEMES UTILISANT CES INSTRUMENTS

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Description

FIELD OF THE INVENTION

[0001]   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

[0002]   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.

[0003]   Surgery is defined as a branch of medicine concerned with diseases requiring operative procedures.

[0004]   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.

[0005]   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.

[0006]   Surgical instruments that incorporate sensors onto the instruments' working surfaces are described, *e.g.*, in U.S. Patent Application No. 10/510,940 and in U.S. Patent 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.

[0007]   Document WO 00/18294 A1 discloses a method for monitoring and evaluating the status of a tumor undergoing treatment including monitoring in vivo at least one physiological parameter associated with a tumor in a subject undergoing treatment, transmitting data from an in situ located sensor to a receiver external of the subject, analyzing the transmitted data, repeating the monitoring and transmitting steps at sequential points in time and evaluating a treatment strategy. The method provides dynamic tracking of the monitored parameters over time. The method can also include identifying in a substantial real time manner when conditions are favorable for treatment and when conditions are unfavorable for treatment and can verify or quantify how much of a known drug dose or radiation dose was actually received at the tumor. The method can include remote transmission from a non-clinical site to allow oversight of the tumor's conditions even during non-active treatment periods (in between active treatments).

[0008]   Further, document US 5,987,346 A, on which document is based the preamble of claim 1 discloses a diagnostic monitor for classifying biological tissue in which a light emitter is optically coupled to the tissue to be diagnosed and a light detector is optically coupled to the tissue to detect a portion of the light which passes through the tissue. The tissue classifier receives a signal from the detector and provides an optical classification output signal, wherein the tissue is classified by type or state, either for detection, localization, or imaging.

[0009]   Document US 5,860,917 A discloses a system for evaluating the response of a patient afflicted with a disease to a therapeutic regimen for the disease.

[0010]   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

[0011]   The invention is defined in claim 1.

[0012]   An advantage of an embodiment 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 an embodiment 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.

[0013]   A further advantage of an embodiment 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.

[0014] A still further advantage of an embodiment 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 an embodiment of the present invention is a system which adapts its guidance based on continuously updated, statistically significant data.

[0015] According to an embodiment of the present invention, the foregoing and other advantages are achieved in part by a system comprising a surgical instrument for manipulating biological tissue during surgery 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. The processor is further configured to predict the likelihood of success of the current procedure being performed on the subject tissue responsive to the comparison.

[0016] According to an example, a system comprises 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.

[0017] According to a further example, a sensor consists 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.

[0018] According to a still further example, a surgical fastening device comprises a sensor for measuring properties of and interaction with a living tissue on the fastening device.

[0019] According to an example, a system comprises 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 proces-

sor 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.

[0020] In another example, a system for monitoring a living tissue of a patient's body, comprises 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.

[0021] Additional advantages of an embodiment 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. The invention is defined in claim 1. Accordingly, the drawings and description are to be regarded as illustrative in nature, and not as restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] 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. 2a shows a right angle surgical stapler according to an embodiment of the present invention.
FIG. 2b shows a linear surgical stapler according to an embodiment of the present invention.
FIG. 2c shows a circular surgical stapler according to an embodiment of the present invention.
FIG. 3a 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. 3b 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. 3c shows sensing elements interleaved with staples in a surgical stapler according to an embodiment of the present invention.
FIGS. 4a-4e show fiber configurations of an optical sensor tip according to embodiments of the present invention.
FIG. 5a is a block diagram of a configuration for transmitting light for the optical sensor of Figs. 4a-4e.
FIG. 5b is a block diagram of a configuration for receiving light for the optical sensor of Figs. 4a-4e.
FIG. 6a is a graph showing the relationship between light absorption and incident wavelength for varying tissue oxygen saturation.

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

FIG. 6c 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. 8a is a graph showing a response to incident light and fluoresced light as fluorescent dye is introduced into a living tissue.

FIG. 8b 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. 10a illustrates a system according to an embodiment of the present invention with light sources and receivers external to an instrument.

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

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

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

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

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

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

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

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

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

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

FIG. 13b 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 EMBODIMENTS OF THE INVENTION

[0023] 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. An embodiment of the present invention addresses and solves these problems stemming from conventional sensing surgical instruments.

[0024] According to an embodiment of 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.

[0025] 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.

[0026] An embodiment of the present invention will now be described in detail with reference to Figs. 1-14.

[0027] 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.

[0028] 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.

[0029]   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.

[0030]   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.

[0031]   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 outcomes 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.

[0032] 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.

[0033] FIGS. 2a-2c depict specific stapler configurations according to embodiments of the present invention. FIG. 2a 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.

[0034] FIG. 2b 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.

[0035] FIG. 2c 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.

[0036] FIGS. 3a-3c 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. 3a 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.

[0037] FIG 3b 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.

[0038] FIG 3c 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.

[0039] FIGS. 4a-4e 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.

[0040] FIG. 4a 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.

[0041] FIG. 4b 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. 4c 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.

[0042] FIG. 4d 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.

[0043] FIG. 4e 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.

[0044] FIG. 5a 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 660nm), near-infrared (near 790nm), and infrared (near 880nm), 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. 4a.

[0045] 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 570nm. 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.

[0046] 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. 4b, 4c, or 4d (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. 4d (emitters as fibers 466) or FIG. 4e.

[0047] FIG. 5b 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. 5a 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, 2D 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, no-

tification, and/or other tasks are performed or directed.

[0048] Light from the emitter described in FIG. 5a 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. 5a.

[0049] FIGS. 6a and 6b show plots that are used to describe oximetry sensing modality. FIG. 6a 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 660nm, 790nm and 880nm 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.

[0050] FIG. 6b shows a plot that represents an experiment used to verify the relationship between oxygen saturation and light absorption. Red light at 660nm represented by 652 and near infrared light at 880nm 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.

[0051] FIG. 6c 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. 6c 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.

[0052] The diagram of FIG. 6c 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 (660nm) and infrared (880nm) light; when a positive voltage 678 is applied, infrared light is emitted, and when a negative voltage 680 is applied, red light is emitted.

[0053] 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.

[0054] 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.

[0055] 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).

[0056] 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. 6c to create a more robust measurement that is invariant to tissue optical density.

[0057] FIGS. 8a-8b 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 520nm) when illuminated with an blue/ultraviolet (peak near 48 8nm) 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.

[0058] FIG. 8a 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.

[0059] FIG. 8b 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.

[0060] 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.

[0061]   FIGS. 10a-10c 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.

[0062]   FIG. 10a 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. 4a-e. The sensor tips transmit the incident light onto tissue 1036 and/or receive the reflected, transmitted, and/or fluoresced light from said tissue.

[0063]   FIG. 10b 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.

[0064]   FIG. 10c 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.

[0065]   FIGS. 11a-11c depict further embodiments of sensing surgical instruments and devices according to the present invention. FIG 11a 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.

[0066]   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, MA. 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.

[0067]   FIG. 11b 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.

[0068]   FIG. 11c 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.

[0069]   FIG. 11d 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.

[0070]   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.

[0071]   In a further embodiment of the system shown in FIG. 11d, 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.

[0072]   FIG. 11e 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. 11e is a representative configuration of the sensor unit; other types, shapes, and configurations are understood to be included as well.

[0073] In further embodiments of the present invention, an absorbable optical fiber (such as shown in Figs. 4a-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.

[0074] FIGS. 12a-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.

[0075] FIG. 12a 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. 12b. 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.

[0076] FIGS. 13a-b depict embodiments where a staple, clip, or other electrode is used for electrical sensing on the surface of a surgical instrument. FIG. 13a 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.

[0077] 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.

[0078] FIG. 13b 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.

[0079] 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.

[0080] FIG. 14 shows a schematic layout of an integrated expert system according to the present invention. The base unit 1401 contains all processing, sensing, con-

trol, 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.

[0081] 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.

[0082] 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.

[0083] 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 confection.

[0084] Embodiments of 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, chemical, processes, etc., in order to provide a thorough understanding of embodiments of the present invention. In other instances, well known processing structures have not been described in detail, in order not to unnecessarily obscure the description of embodiments of the present invention.

[0085] Only an exemplary embodiment of the present invention and but a few examples of its versatility are shown and described in the present disclosure.

Claims

1. A system comprising:

a surgical instrument for manipulating biological tissue during surgery 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 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,

characterized in that the processor is further configured to predict the likelihood of success

of the current procedure being performed on the subject tissue responsive to the comparison.

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

3. The system of claim 2, wherein the processor is further configured to add 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 to the memory.

4. The system of claim 1, further comprising a communications device for communicating 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.

5. The system of claim 4, 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.

6. The system of claim 1, further comprising a communications device for communicating 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.

7. The system of claim 6, 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.

8. 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, a trochar, a sensing sleeve, and an independent sensor.

9. The system of claim 1, further comprising a reference measurement instrument having a sensor for measuring a reference tissue and generating a reference measurement signal;
wherein the reference tissue is a tissue of the patient;
wherein the signal processor is for converting 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.

10. The system of claim 1, further comprising a robotic manipulator for controlling the surgical instrument.

11. The system of claim 2, further comprising patient monitoring equipment for generating patient condition data and transferring 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.

12. The system of claim 2, further comprising patient status sensing equipment for generating patient status data and transferring 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.

13. The system of claim 1, wherein the sensor is for generating signals before, during and after actuation of the surgical instrument, and the signal processor is for processing such signals and including such signals in the dataset.

14. The system of claim 1 further comprising:

a reference measurement instrument having a sensor for measuring a reference tissue and generating a reference measurement signal;
wherein the signal processor is further adapted for receiving the reference measurement signal and converting it into a current reference dataset;
wherein the memory is further adapted for storing the current reference dataset; and
wherein the processor is configured to compare the current dataset with the current reference dataset, and to assess a physical condition of the subject tissue or guide a current procedure being performed on the tissue, responsive to the comparison.

15. The system of claim 14, wherein the signal processor is for converting 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.

16. The system of claim 1, wherein the surgical instrument comprises a stapler.

Patentansprüche

1. Ein System, das Folgendes umfasst:

ein chirurgisches Instrument zur Manipulation von biologischem Gewebe während eines chirurgischen Eingriffs bzw. einer chirurgischen Prozedur, das einen Sensor zur Erzeugung eines Signals aufweist, der eine Eigenschaft des Zielgewebes des Patienten angibt;
ein Signalprozessor, um das Signal zu empfangen und das Signal in einen aktuellen Datensatz zu konvertieren;
einen Speicher zur Speicherung des aktuellen Datensatzes; und
einen Prozessor, der konfiguriert ist, um den aktuellen Datensatz mit anderen zuvor im Speicher gespeicherten Datensätzen zu vergleichen, und um eine körperliche Verfassung des Zielgewebes zu beurteilen oder um, in Antwort auf den Vergleich, einen laufenden Eingriff zu leiten, der am Gewebe ausgeführt wird, **dadurch gekennzeichnet, dass** der Prozessor des Weiteren konfiguriert ist, um bei dem am Gewebe ausgeführten laufenden Eingriff, entsprechend dem Vergleich, die Aussicht auf Erfolg zu prognostizieren.

2. Das System nach Anspruch 1, wobei der Speicher Daten enthält, die sich auf mindestens eines der Folgenden beziehen: unmittelbare Ergebnisse, kurzfristige Ergebnisse, langfristige Ergebnisse früherer Eingriffsvorgänge (*instances of the procedure*), und wobei der Prozessor konfiguriert ist, um die Aussicht auf Erfolg bei dem laufenden Eingriff in Antwort auf die Daten zu prognostizieren, die sich auf die Ergebnisse beziehen, und wobei er des Weiteren Daten beinhaltet, mit Bezug auf den Zeitraum vor dem Eingriff, während des Eingriffs, nach dem Eingriff.

3. Das System nach Anspruch 2, wobei der Prozessor des Weiteren dazu konfiguriert ist, dem Speicher mindestens einen der Folgenden hinzuzufügen: Daten mit Bezug auf den Zeitraum vor dem Eingriff, während des Eingriffs, nach dem Eingriff, unmittelbare Ergebnisse, kurzfristige Ergebnisse, langfristige Ergebnisse des aktuellen Eingriffs.

4. Das System nach Anspruch 1, das des Weiteren eine Vorrichtung zur Kommunikation umfasst, um mit einer entfernten Datenbank zu kommunizieren, die zuvor gespeicherte Datensätze und Daten umfasst, die sich auf Ergebnisse früherer Vorgänge des Eingriffs beziehen;
wobei der Prozessor dazu konfiguriert ist, den aktuellen Datensatz mit den Datensätzen und Daten der entfernten Datenbank zu vergleichen.

5. Das System nach Anspruch 4, wobei der Prozessor des Weiteren dazu konfiguriert ist, die entfernte Datenbank unter Verwendung des aktuellen Datensatzes und mindestens einen der Folgenden zu aktualisieren: Daten mit Bezug auf den Zeitraum vor dem Eingriff, während des Eingriffs, nach dem Eingriff, unmittelbare Ergebnisse, kurzfristige Ergebnisse, langfristige Ergebnisse des aktuellen Eingriffs.

6. Das System nach Anspruch 1, das des Weiteren eine Vorrichtung zur Kommunikation umfasst, um mit einem Datenspeicher des Patienten zu kommunizieren, der die Krankengeschichte des Patienten umfasst, der sich dem aktuellen Eingriff unterzieht;
wobei der Prozessor dazu konfiguriert ist, die Erfolgsaussicht des aktuellen Eingriffs entsprechend der Krankengeschichte des Patienten zu prognostizieren.

7. Das System nach Anspruch 6, wobei der Prozessor des Weiteren dazu konfiguriert ist, die Krankengeschichte des Patienten unter Verwendung des aktuellen Datensatzes und dem Ergebnis des aktuellen Eingriffs zu aktualisieren.

8. Das System nach Anspruch 1, wobei das chirurgische Instrument mindestens einen der Folgenden beinhaltet: ein chirurgisches Klammergerät, eine Anbringvorrichtung für Klemmen, ein Greifinstrument, ein Retraktor bzw. Wundspreizer, ein Skalpell, eine Zange, ein laparoskopisches Werkzeug, ein offenes chirurgisches Werkzeug (*open surgical tool),* ein Kauterisationswerkzeug, ein Roboterwerkzeug, eine Schere, eine Klemme, eine Nadel, einen Katheter, einen Trokar, eine Erfassungshülse (*sensing sleeve),* und ein unabhängiger Sensor.

9. Das System nach Anspruch 1, das des Weiteren ein Referenz-Messinstrument umfasst, das einen Sensor aufweist, zur Messung eines Referenzgewebes und zur Erzeugung eines Referenz-Messsignals;
wobei das Referenzgewebe ein Gewebe des Patienten ist;
wobei der Signalprozessor zur Konversion des Referenz-Messsignals in einen Referenzgrundlinien-Messdatensatz anwesend ist, und der Prozessor dazu konfiguriert ist, abhängig vom Referenzgrundlinien-Messdatensatz, die körperliche Verfassung des Zielgewebes zu beurteilen.

10. Das System nach Anspruch 1, das des Weiteren einen Manipulator-Roboter zur Steuerung des chirurgischen Instruments umfasst.

11. Das System nach Anspruch 2, das des Weiteren Geräte zur Überwachung des Patienten umfasst, um Patientenzustands-Daten zu erzeugen und um die Patientenzustands-Daten an den Prozessor zu übertragen,
wobei der Prozessor dazu konfiguriert ist, die Verfassung des Gewebes zu beurteilen und die Erfolgsaussicht des aktuellen Eingriffs entsprechend der Patientenzustands-Daten zu prognostizieren.

12. Das System nach Anspruch 2, das des Weiteren Patientenstatus-Erfassungsgeräte umfasst, um Patientenstatus-Daten zu erzeugen und um die Patientenstatus-Daten an den Prozessor zu übertragen,
wobei der Prozessor dazu konfiguriert ist, die Verfassung des Gewebes zu beurteilen, den aktuellen Eingriff zu leiten oder die Erfolgsaussicht des aktuellen Eingriffs entsprechend der Patientenstatus-Daten zu prognostizieren.

13. Das System nach Anspruch 1, wobei der Sensor dazu anwesend ist, um Signale vor, während und nach der Betätigung des chirurgischen Instruments zu erzeugen, und der Prozessor dazu anwesend ist, diese Signale zu verarbeiten und diese Signale in den Datensatz zu integrieren.

14. Das System nach Anspruch 1, das des Weiteren Folgendes umfasst:

ein Referenz-Vermessungsinstrument, das einen Sensor aufweist zur Vermessung eines Referenzgewebes und zur Erzeugung eines Referenz-Vermessungssignals;
wobei der Signalprozessor des Weiteren dazu angepasst ist, das Referenz-Vermessungssignal zu empfangen und es in einen aktuellen Referenz-Datensatz zu konvertieren;
wobei der Speicher des Weiteren dazu angepasst ist, den aktuellen Referenz-Datensatz zu speichern; und
wobei der Prozessor konfiguriert ist, um den aktuellen Datensatz mit dem aktuellen Referenz-Datensatz zu vergleichen, und um eine Verfassung des Zielgewebes zu beurteilen oder einen am Gewebe ausgeführten aktuellen Eingriff entsprechend dem Vergleich zu leiten.

15. Das System nach Anspruch 14, wobei der Signalprozessor dazu vorgesehen ist, das Referenz-Vermessungssignal in einen Referenzgrundlinien-Messdatensatz zu konvertieren, und wobei der Prozessor konfiguriert ist, um eine Verfassung des Zielgewebes entsprechend dem Referenzgrundlinien-

Messdatensatz zu beurteilen.

16. Das System nach Anspruch 1, wobei das chirurgische Instrument ein Klammergerät umfasst.

Revendications

1. Un système, comprenant :

un instrument chirurgical pour la manipulation d'un tissu biologique pendant une intervention chirurgicale, présentant un capteur pour générer un signal indiquant une propriété d'un tissu cible d'un patient ;
un processeur de signaux pour recevoir le signal et convertir le signal en un ensemble de données actuel ;
une mémoire pour stocker l'ensemble de données actuel ; et
un processeur configuré pour comparer l'ensemble de données actuel avec d'autres ensembles de données stockés au préalable dans la mémoire, et pour évaluer une condition physique du tissu cible ou pour guider une procédure actuelle effectuée sur le tissu, en réponse à la comparaison,
caractérisé en ce que le processeur est en outre configuré pour pronostiquer les chances de succès de la procédure actuelle effectuée sur le tissu cible, en réponse à la comparaison.

2. Le système d'après la revendication 1, sachant que la mémoire contient des données relatives à au moins une parmi les suivantes : des résultats immédiats, des résultats à court terme, des résultats à long terme relatifs à une occurrence antérieure de la procédure, et que le processeur est configuré pour pronostiquer les chances de succès de la procédure actuelle en réponse aux données concernant les résultats, et qu'elle peut en outre contenir des données concernant des données avant la procédure, des données pendant la procédure, des données après la procédure.

3. Le système d'après la revendication 2, sachant que le processeur est en outre configuré pour ajouter à la mémoire au moins un des suivants : des données avant la procédure, des données pendant la procédure, des données après la procédure, des résultats immédiats, des résultats à court terme, des résultats à long terme de la procédure actuelle.

4. Le système d'après la revendication 1, comprenant en outre un dispositif de communication pour communiquer avec une base de données distante qui comprend des ensemble de données précédemment stockés et des données concernant des résul-

tats d'occurrences antérieures de la procédure ; sachant que le processeur est configuré pour comparer l'ensemble de données actuel avec les ensembles de données et les données de la base de données distante.

5. Le système d'après la revendication 4, sachant que le processeur est en outre configuré pour actualiser la base de données distante en utilisant l'ensemble de données actuel et au moins un des suivants : des données avant la procédure, des données pendant la procédure, des données après la procédure, des résultats immédiats, des résultats à court terme, des résultats à long terme de la procédure actuelle.

6. Le système d'après la revendication 1, comprenant en outre un dispositif de communication pour communiquer avec un magasin de données de patient comprenant l'historique médical du patient soumis à la procédure actuelle ; sachant que le processeur est configuré pour pronostiquer les chances de succès de la procédure actuelle en réponse à l'historique médical du patient.

7. Le système d'après la revendication 6, sachant que le processeur est en outre configuré pour actualiser l'historique médical du patient en utilisant l'ensemble de données actuel et le résultat immédiat de la procédure actuelle.

8. Le système d'après la revendication 1, sachant que l'instrument chirurgical inclut au moins un des suivants : une agrafeuse chirurgicale, un applicateur d'agrafes, un dispositif de préhension, un rétracteur, un scalpel, une pince (*forceps*), un outil laparoscopique, un instrument chirurgical ouvert (*open surgical tool*), un outil de cautérisation, un outil robotique, des ciseaux, une pince (*clamp*), une aiguille, un cathéter, un trocart, une gaine de détection (*sensing sleeve),* et un capteur indépendant.

9. Le système d'après la revendication 1, comprenant en outre un instrument de mesure de référence présentant un capteur pour mesurer un tissu de référence et générer un signal de mesure de référence ; sachant que le tissu de référence est un tissu du patient ; sachant que le processeur de signaux est destiné à la conversion du signal de mesure de référence en un ensemble de données de mesure de base de référence, et que le processeur est configuré pour évaluer la condition physique du tissu cible en réponse à l'ensemble de données de mesure de base de référence.

10. Le système d'après la revendication 1, comprenant en outre un manipulateur robotique pour commander l'instrument chirurgical.

11. Le système d'après la revendication 2, comprenant en outre un équipement de surveillance de patient pour générer des données de condition de patient et transférer les données de condition de patient au processeur, sachant que le processeur est configuré pour évaluer la condition du tissu et pour pronostiquer les chances de succès de la procédure actuelle en réponse aux données de condition de patient.

12. Le système d'après la revendication 2, comprenant en outre un équipement de détection d'état de patient pour générer des données d'état de patient et transférer les données d'état de patient au processeur, sachant que le processeur est configuré pour évaluer la condition du tissu, guider la procédure actuelle ou pour pronostiquer les chances de succès de la procédure actuelle en réponse aux données d'état de patient.

13. Le système d'après la revendication 1, sachant que le capteur est destiné à générer des signaux avant, pendant et après l'actionnement de l'instrument chirurgical, et que le processeur de signaux est destiné au traitement de ces signaux et à l'inclusion des ces signaux dans l'ensemble de données.

14. Le système d'après la revendication 1, comprenant en outre :

un instrument de mesure de référence présentant un capteur pour mesurer un tissu de référence et pour générer un signal de mesure de référence ; sachant que le processeur de signaux est en outre adapté pour recevoir le signal de mesure de référence et pour le convertir en un ensemble de données de référence actuel ; sachant que la mémoire est en outre adaptée pour stocker l'ensemble de données de référence actuel ; et sachant que le processeur est configuré pour comparer l'ensemble de données actuel avec l'ensemble de données de référence actuel, et pour évaluer une condition physique du tissu cible ou pour guider une procédure actuelle effectuée sur le tissu en réponse à la comparaison.

15. Le système d'après la revendication 14, sachant que le processeur de signaux est destiné à la conversion du signal de mesure de référence en un ensemble de données de mesure de base de référence, et que le processeur est configuré pour évaluer la condition physique du tissu cible en réponse à l'ensemble de données de mesure de base de référence.

16. Le système d'après la revendication 1, sachant que

l'instrument chirurgical comprend une agrafeuse.

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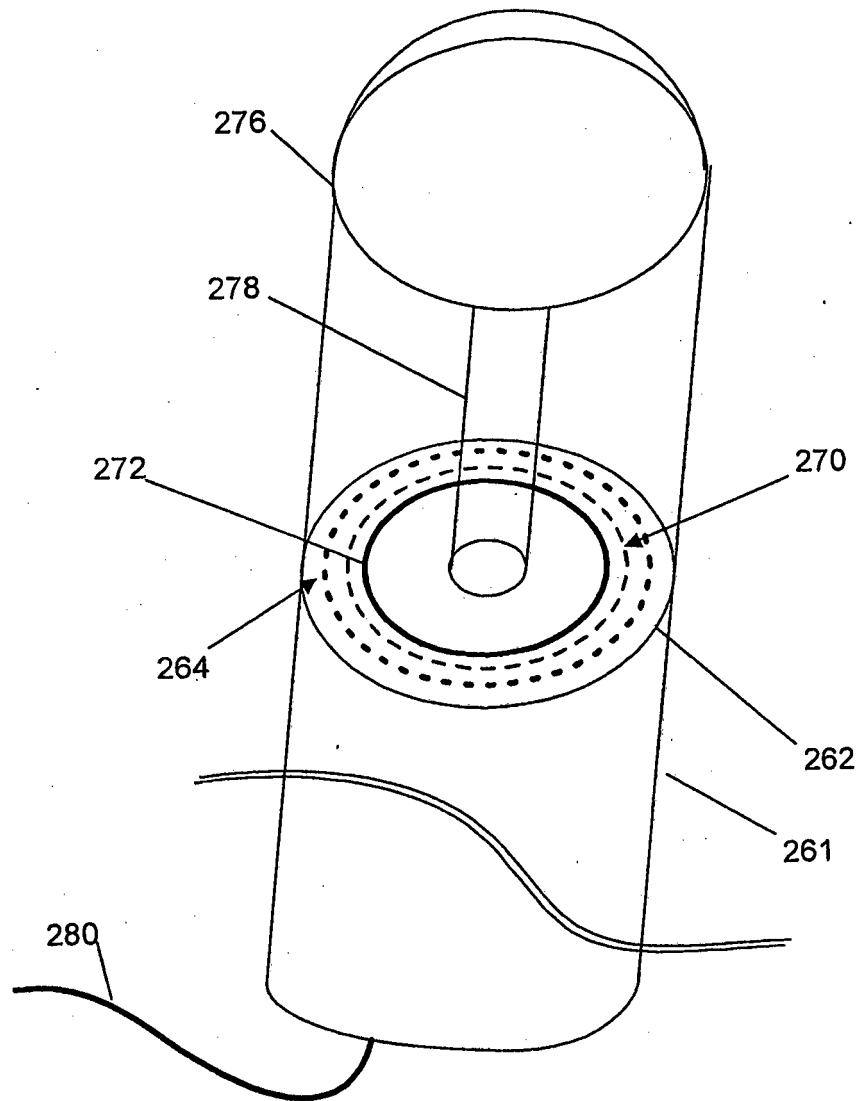*10*

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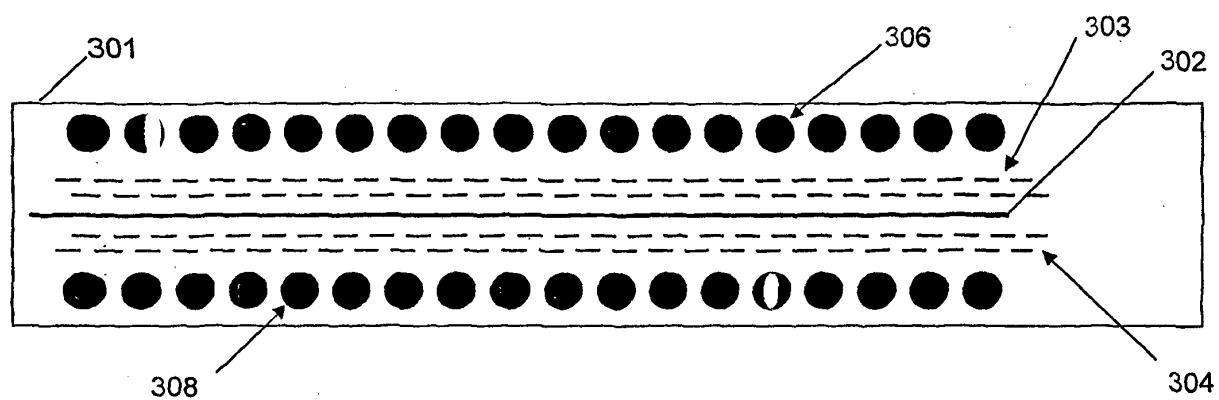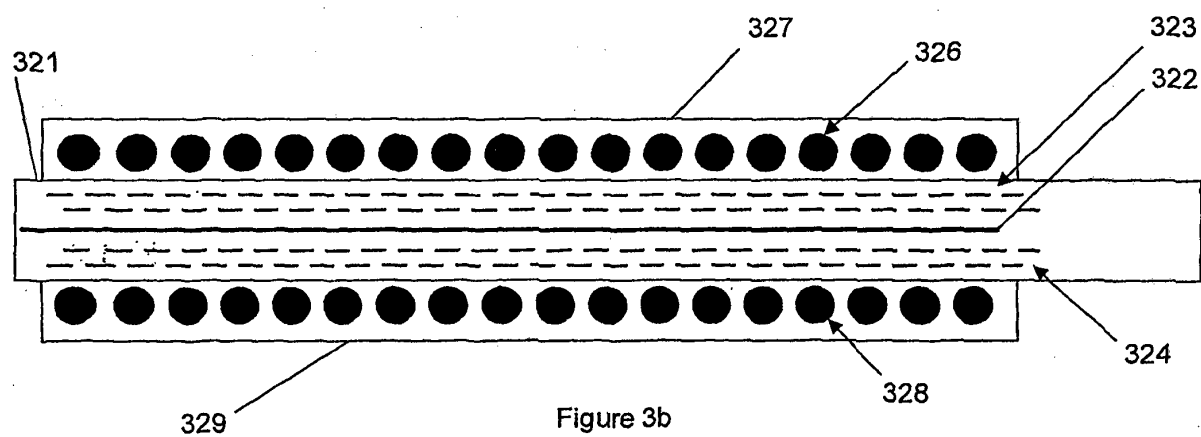*35*

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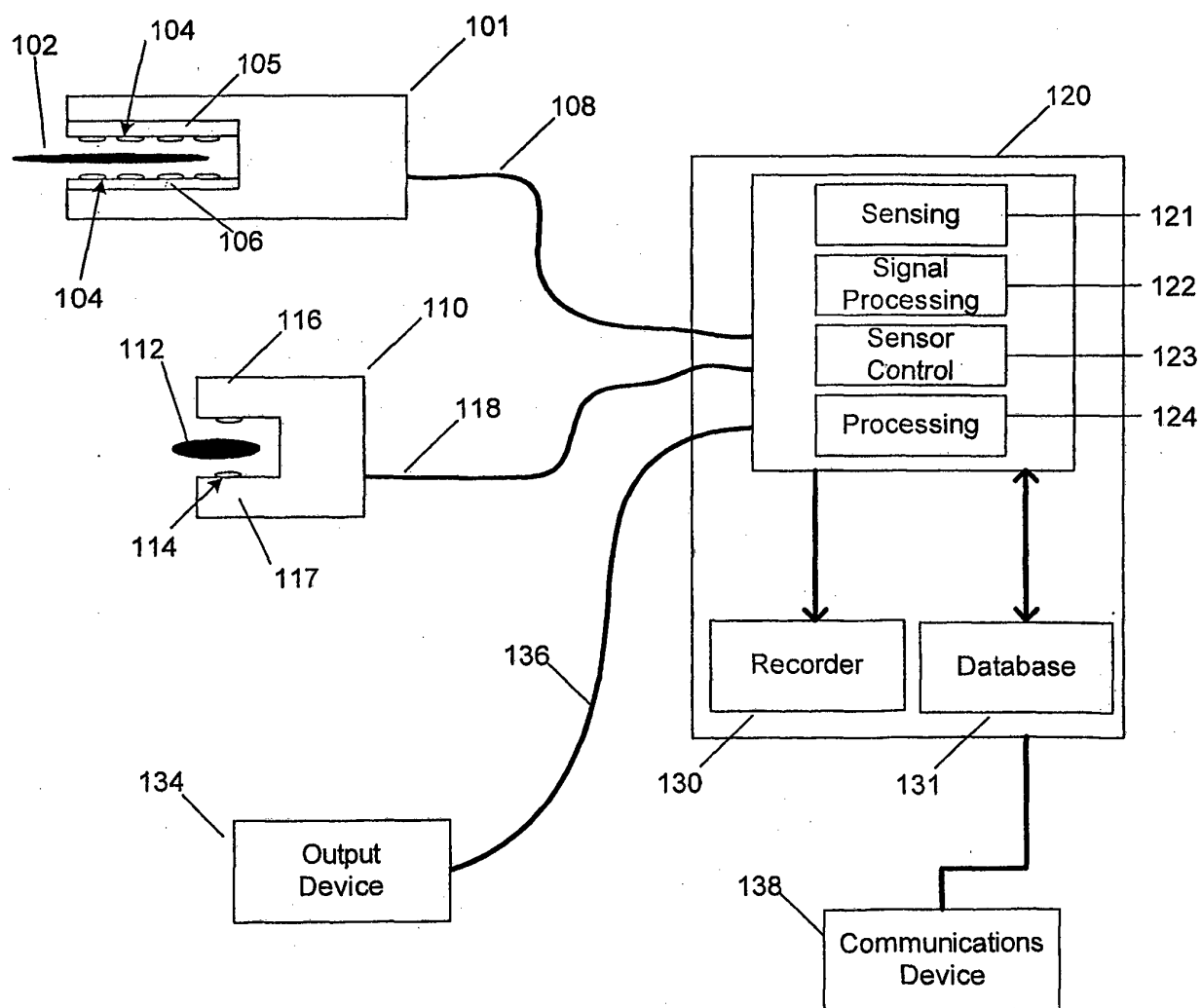
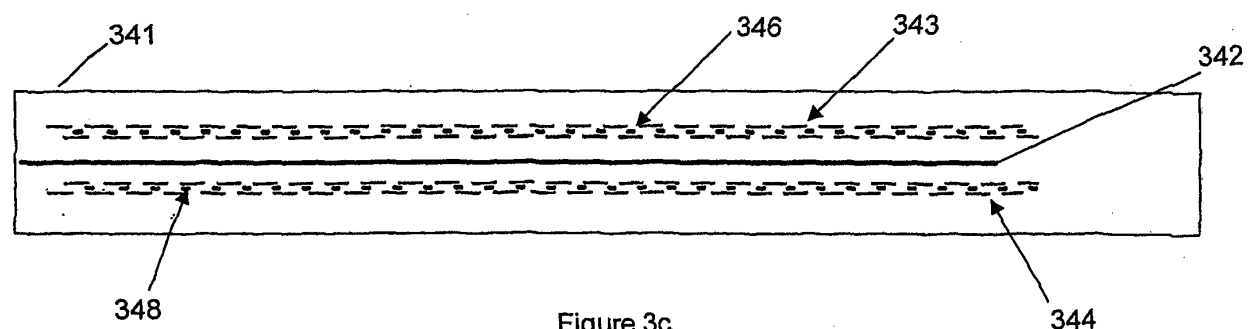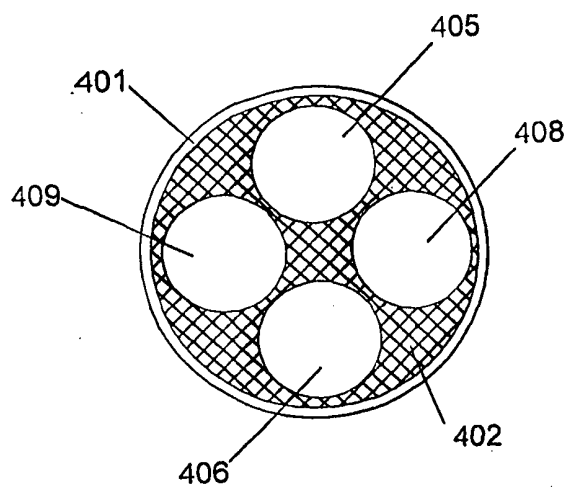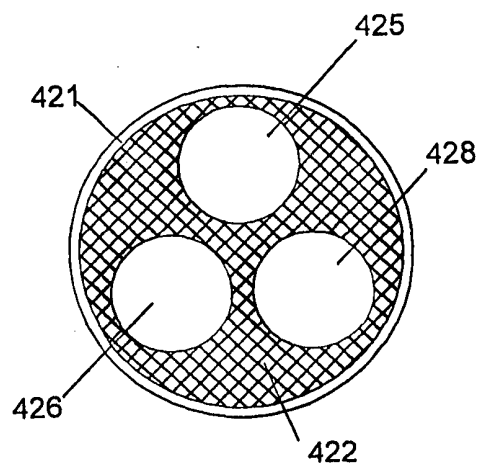Figure 1
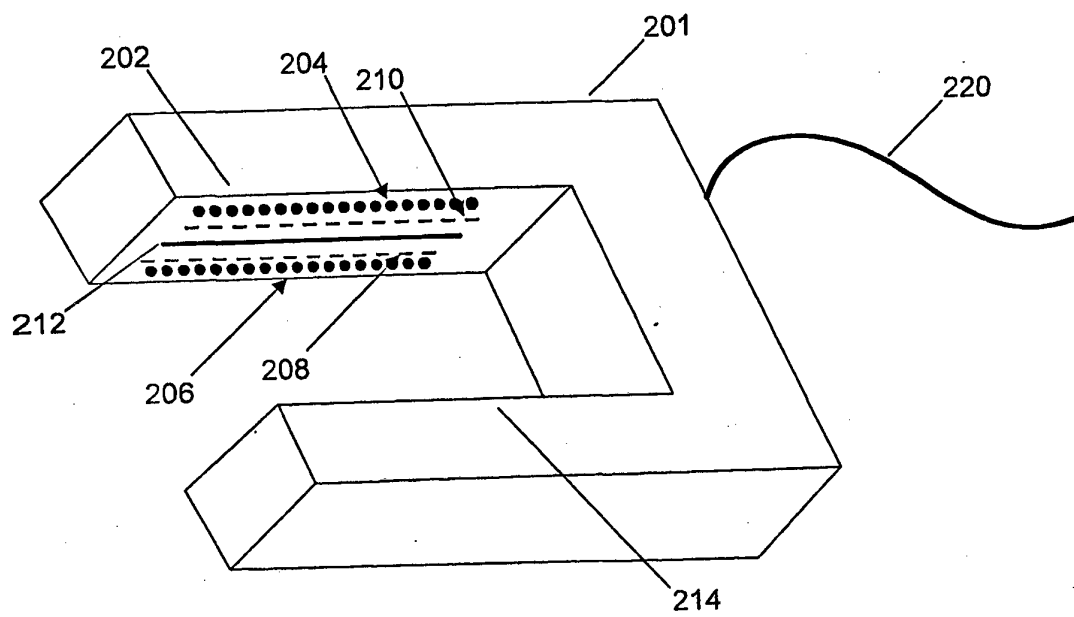
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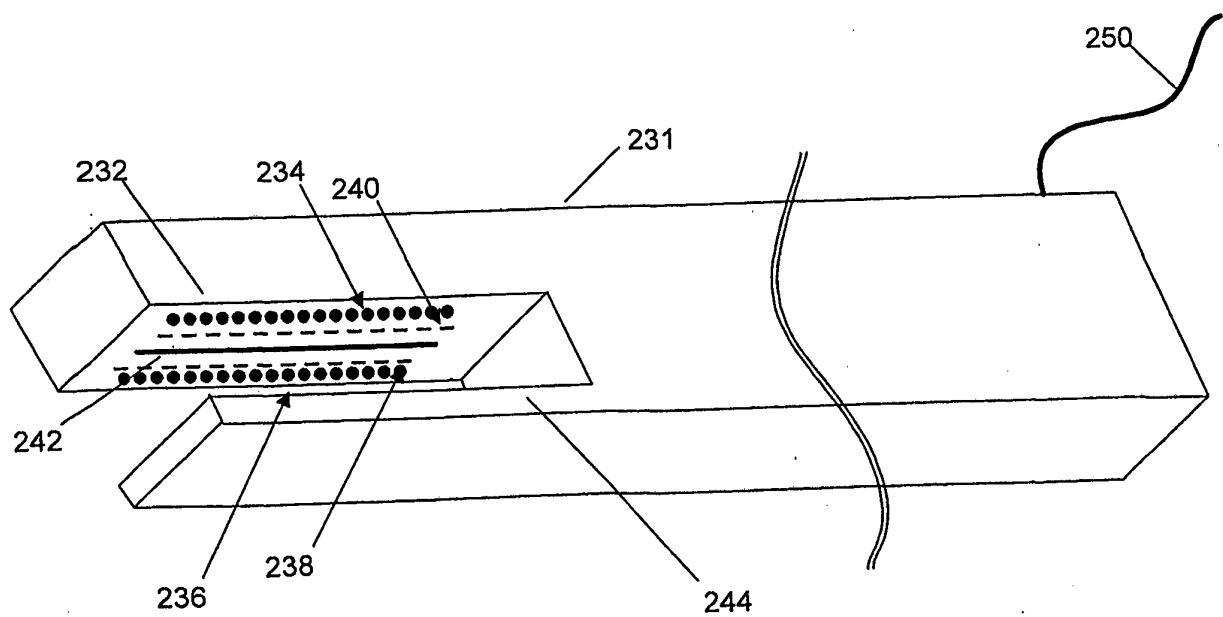
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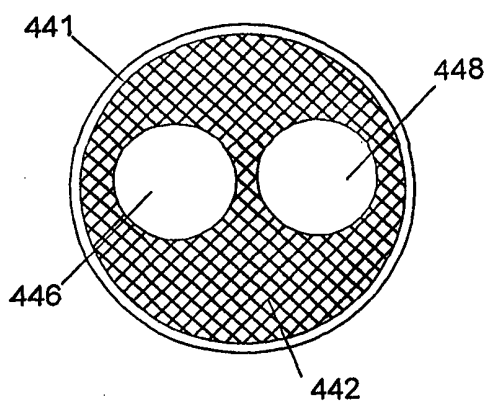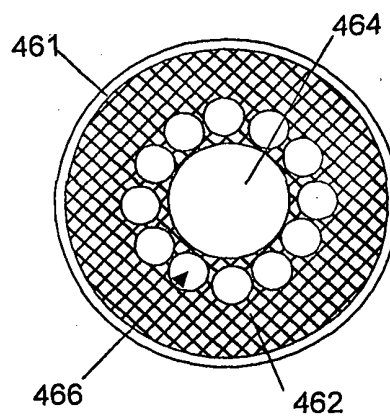
Figure 2c

Figure 3a

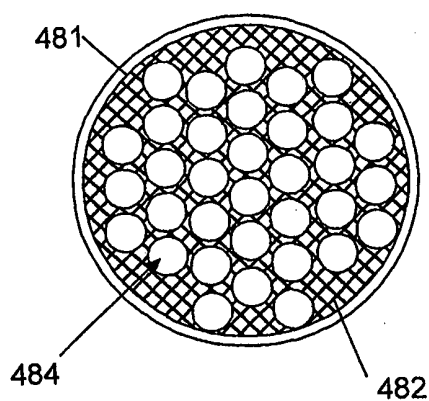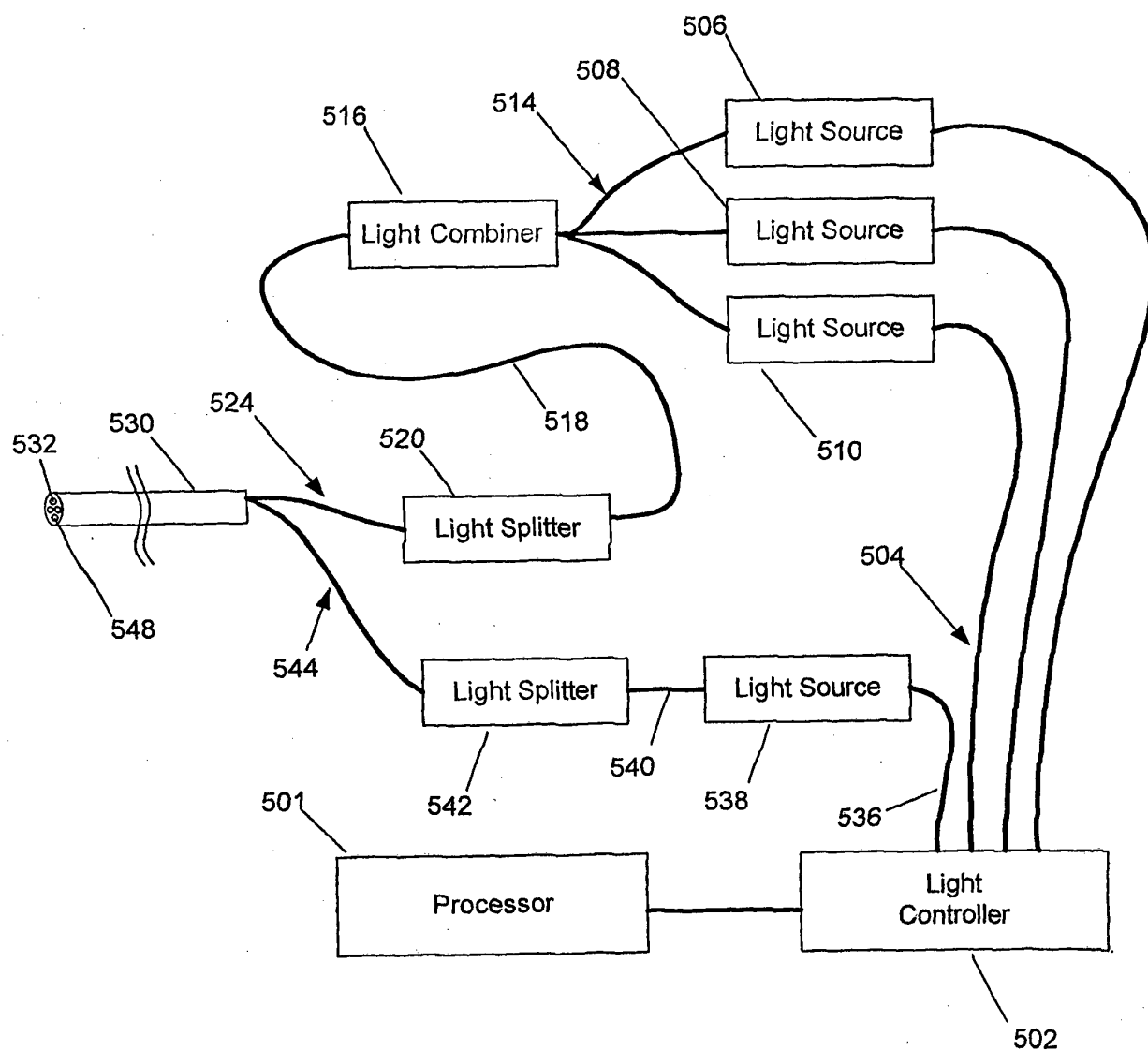Figure 3b

Figure 3c

Figure 4a
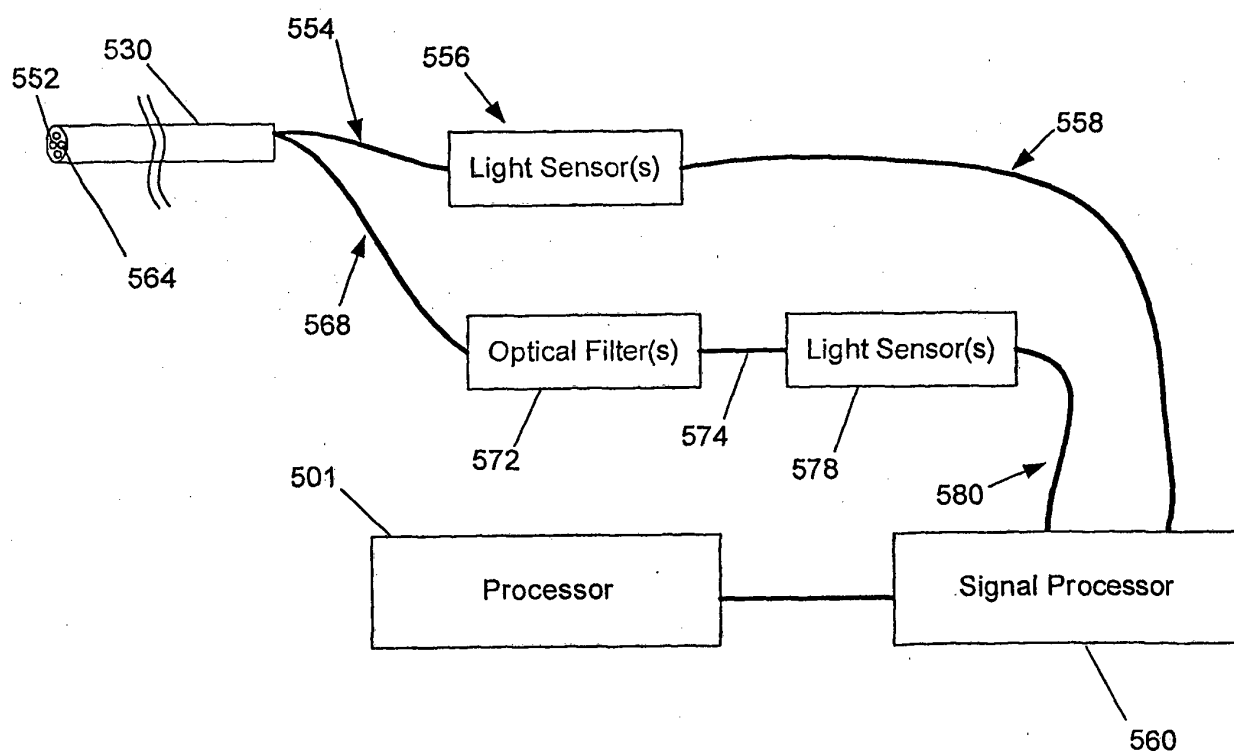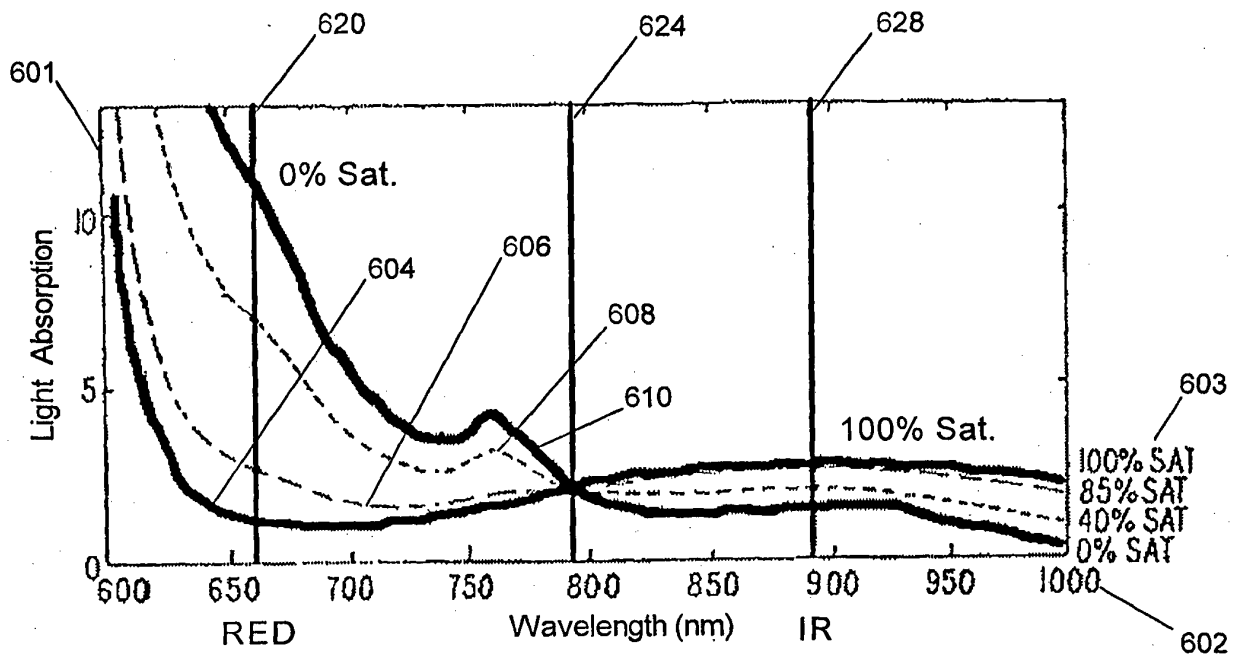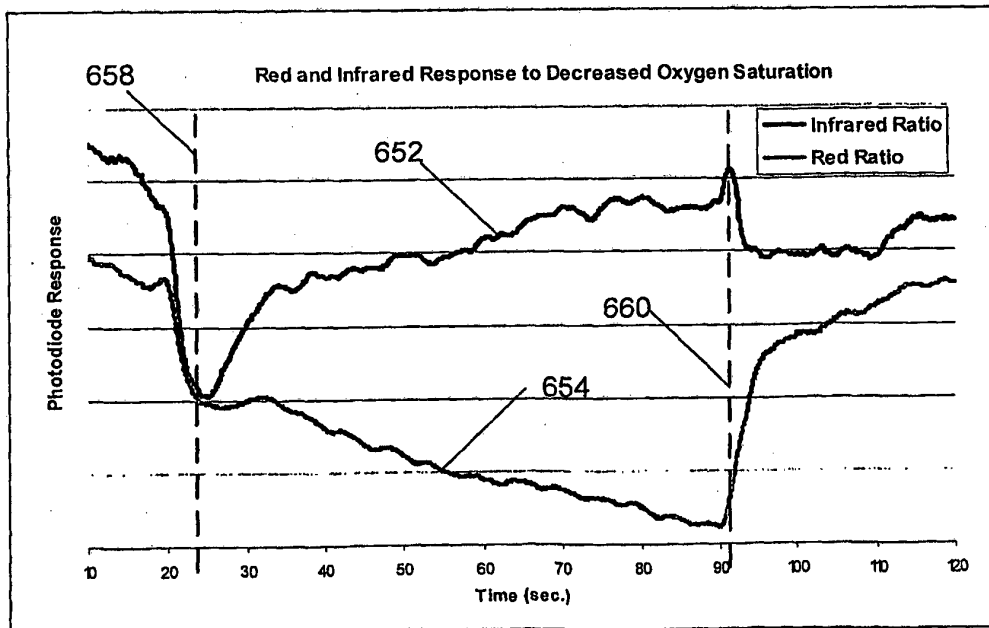
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Figure 4c

Figure 4d
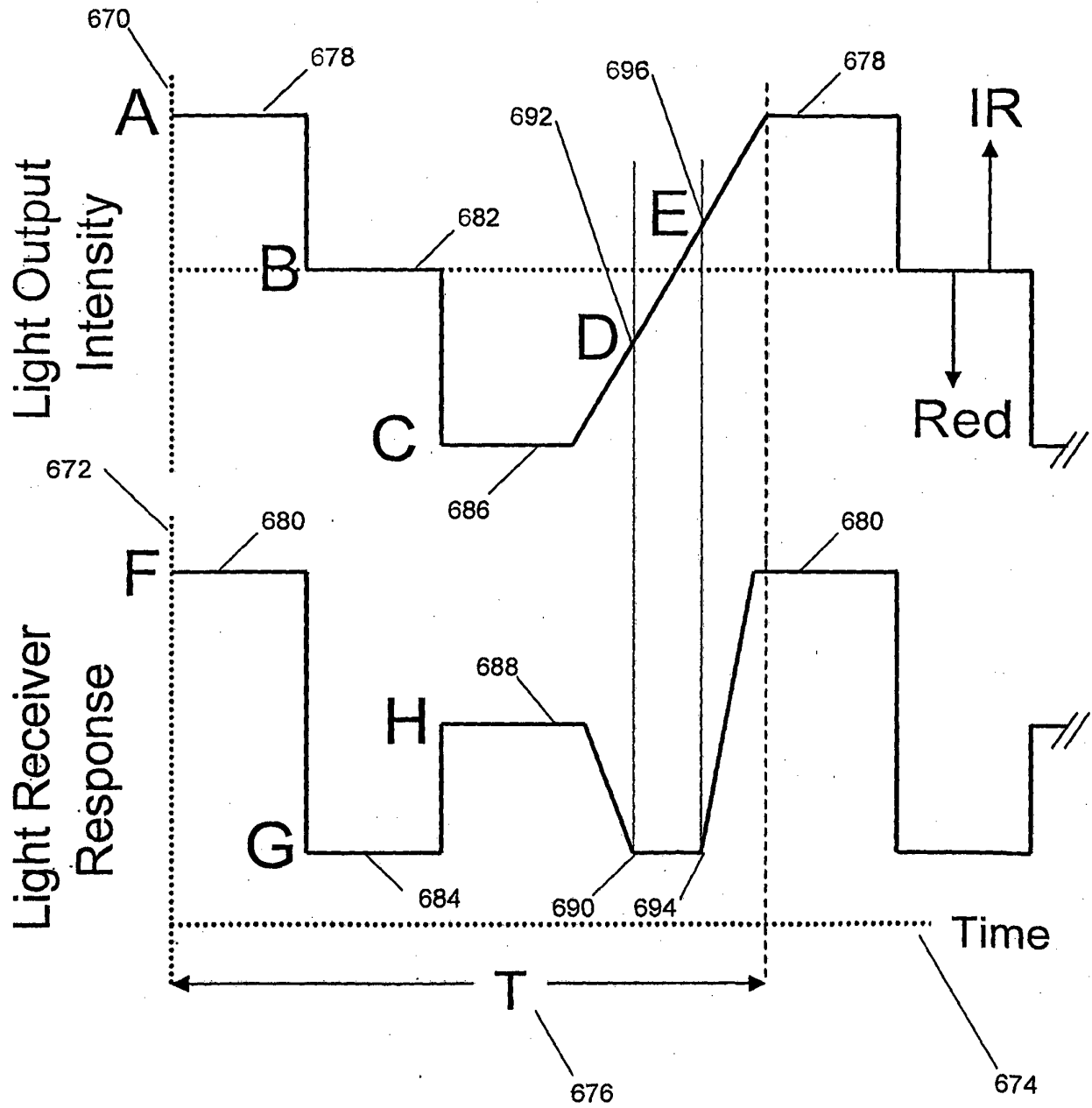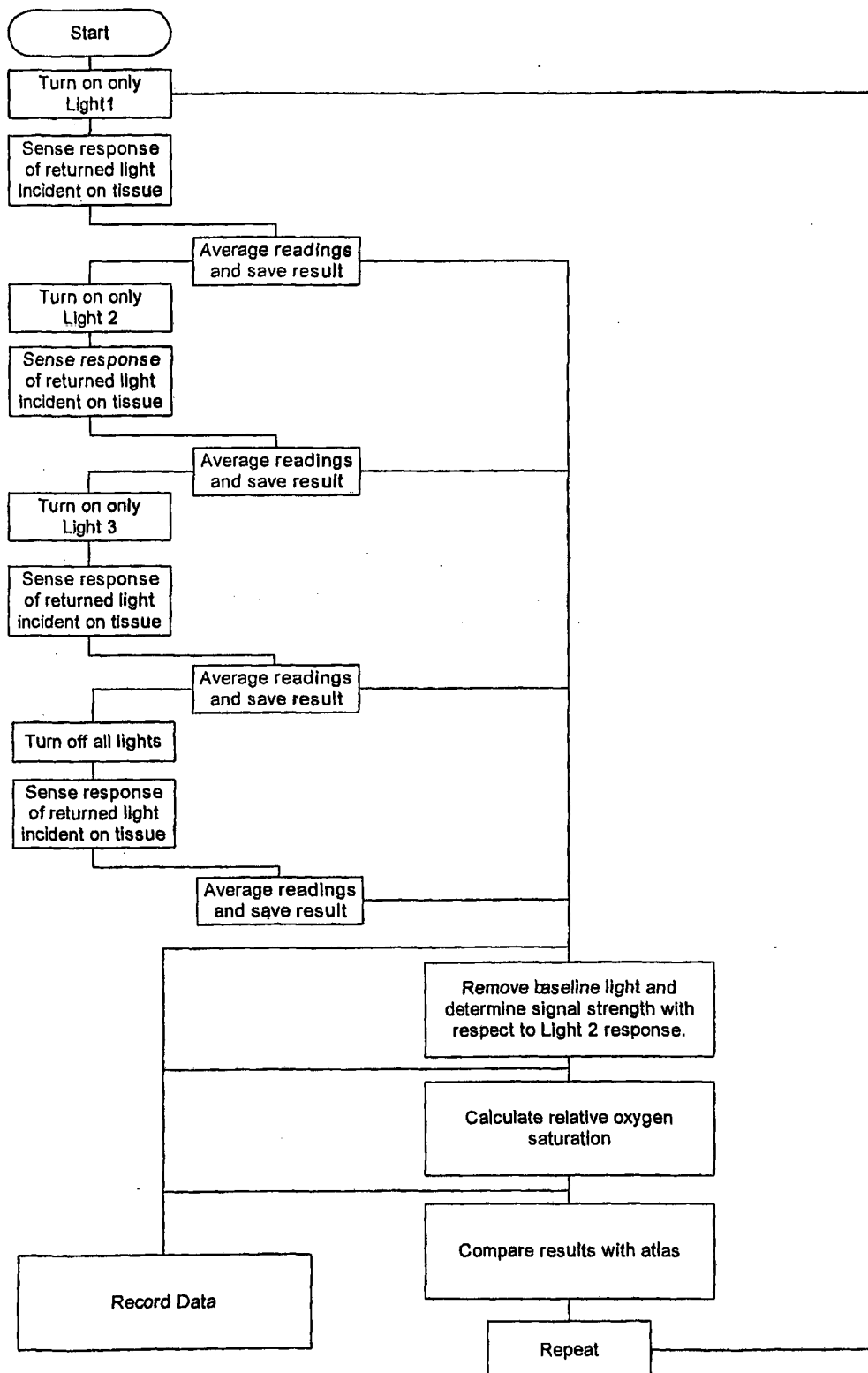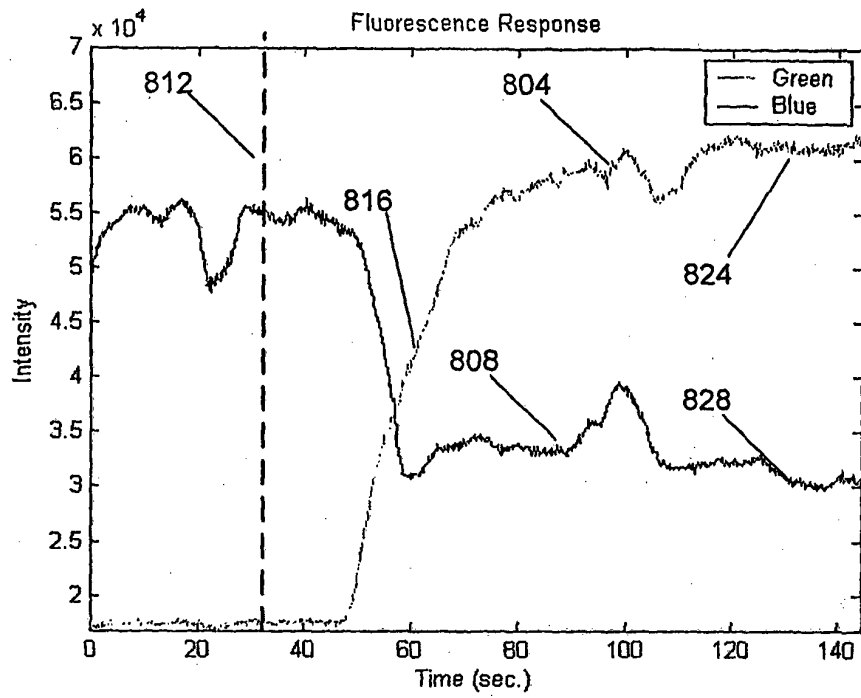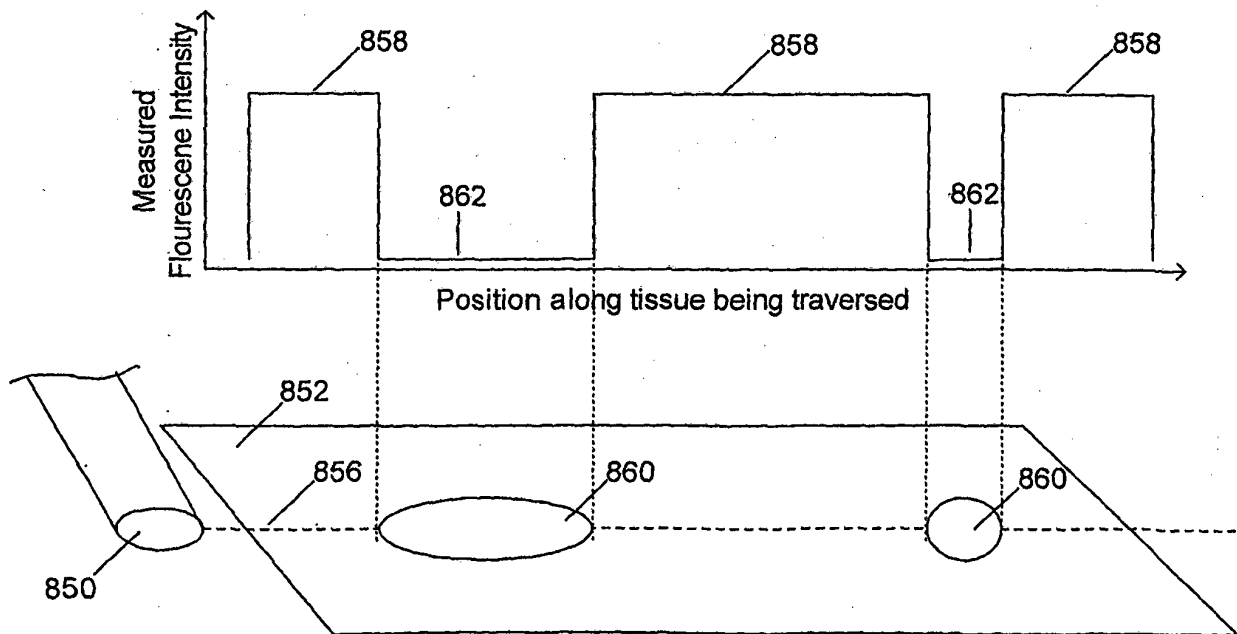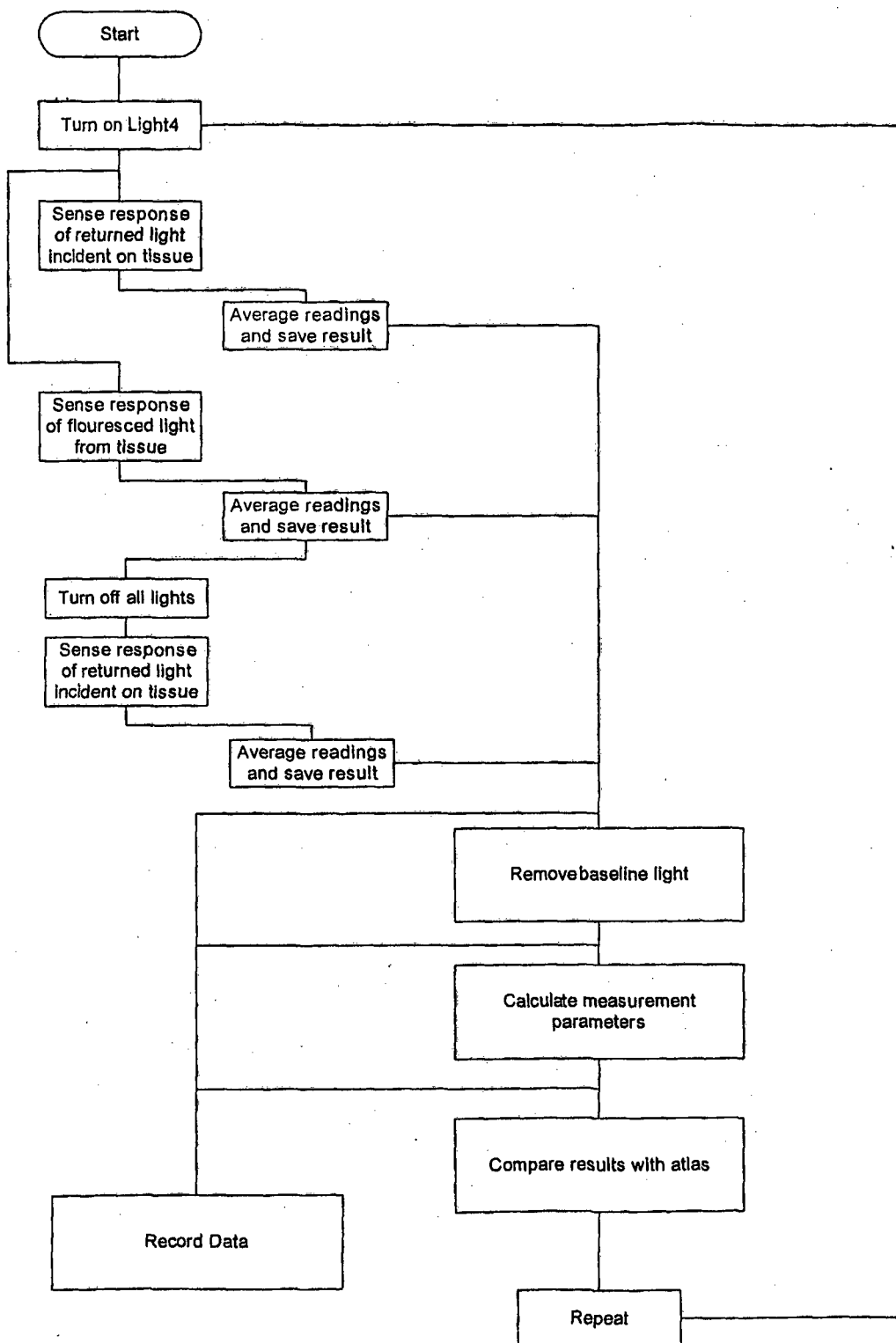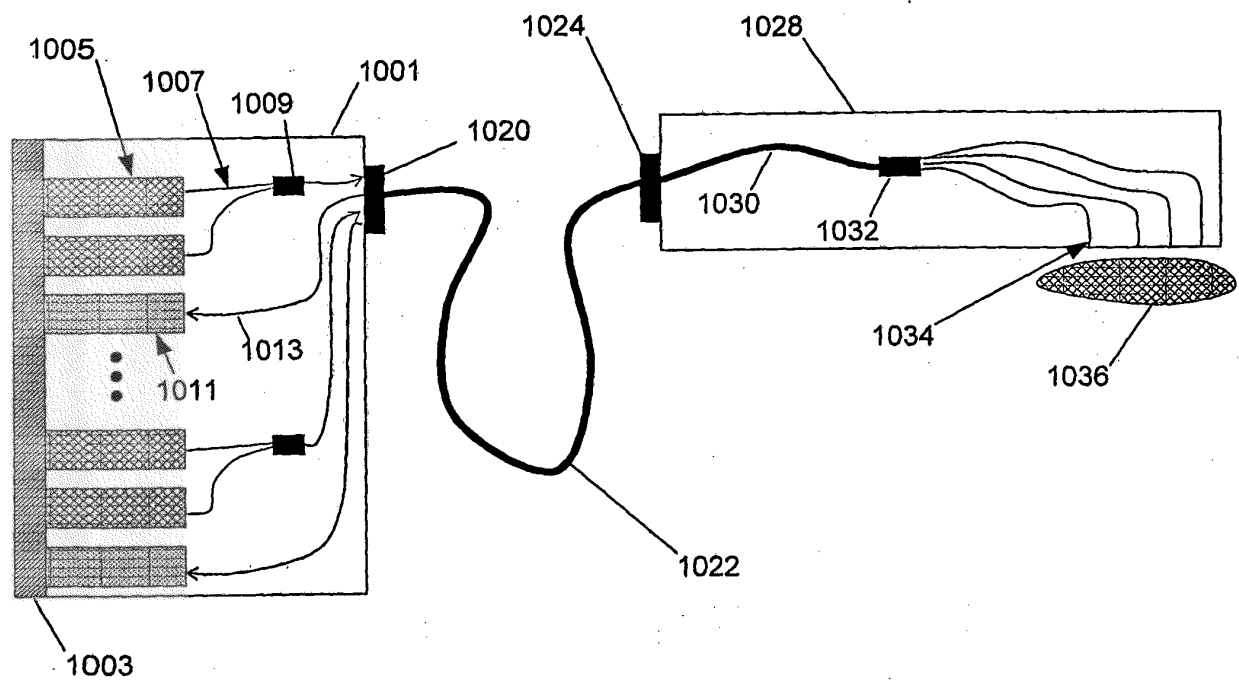
Figure 4e

Figure 5a

Figure 5b

Figure 6a
(Prior Art)

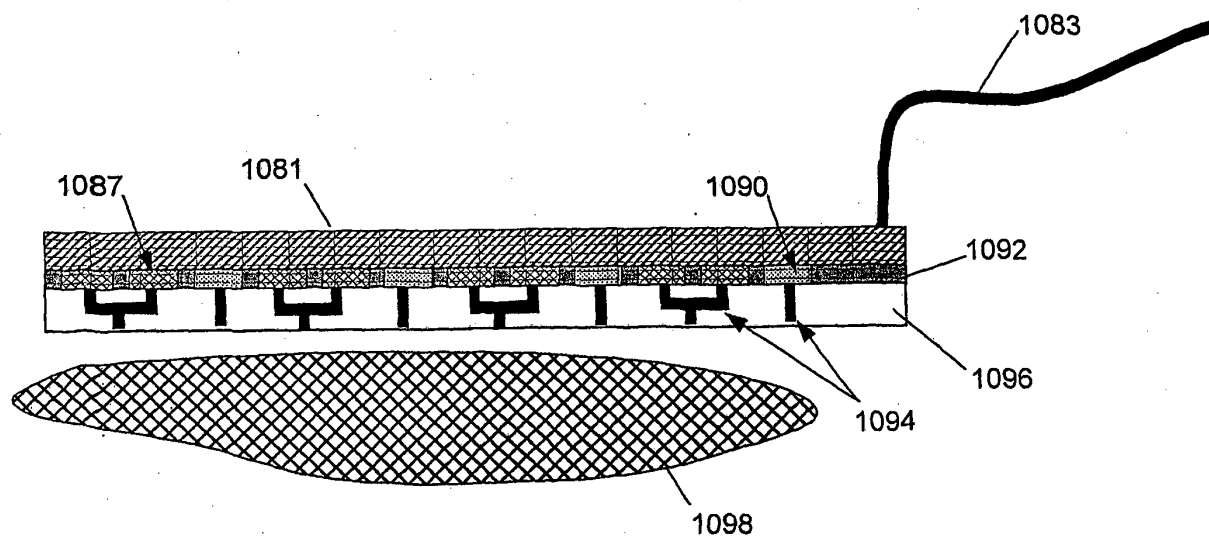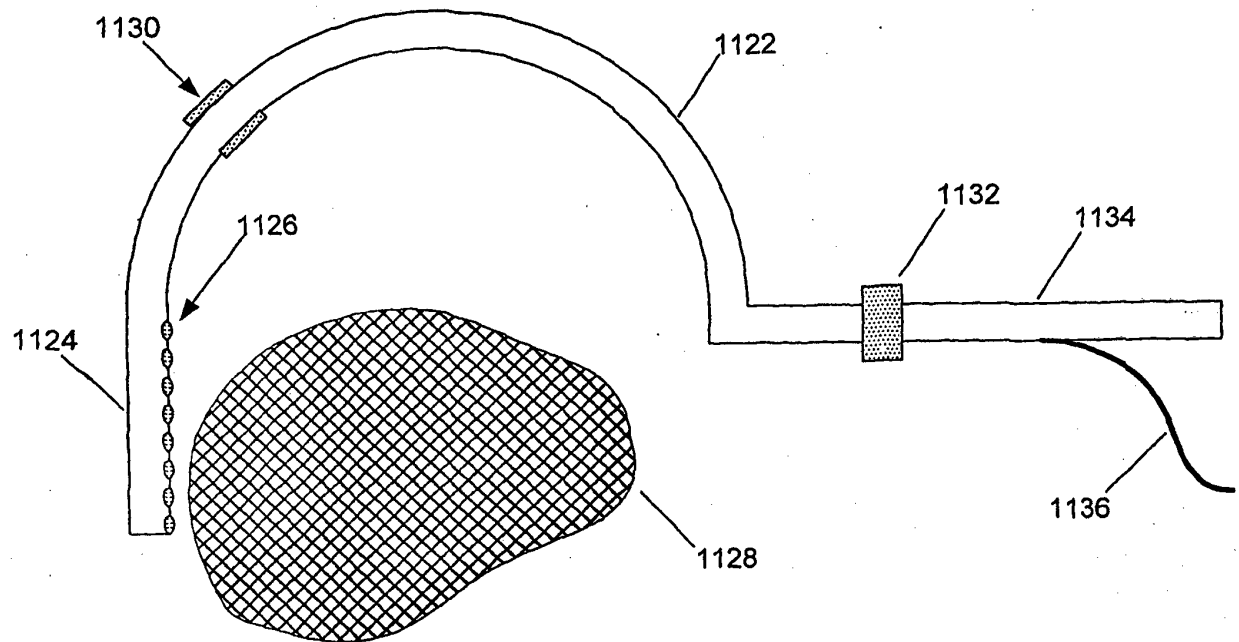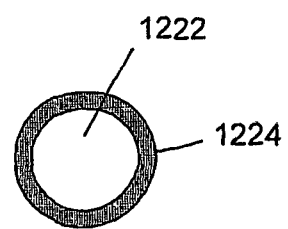

Figure 6b

Figure 6c

Figure 7

Figure 8a

Figure 8b

Figure 9

Figure 10a

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Figure 10b

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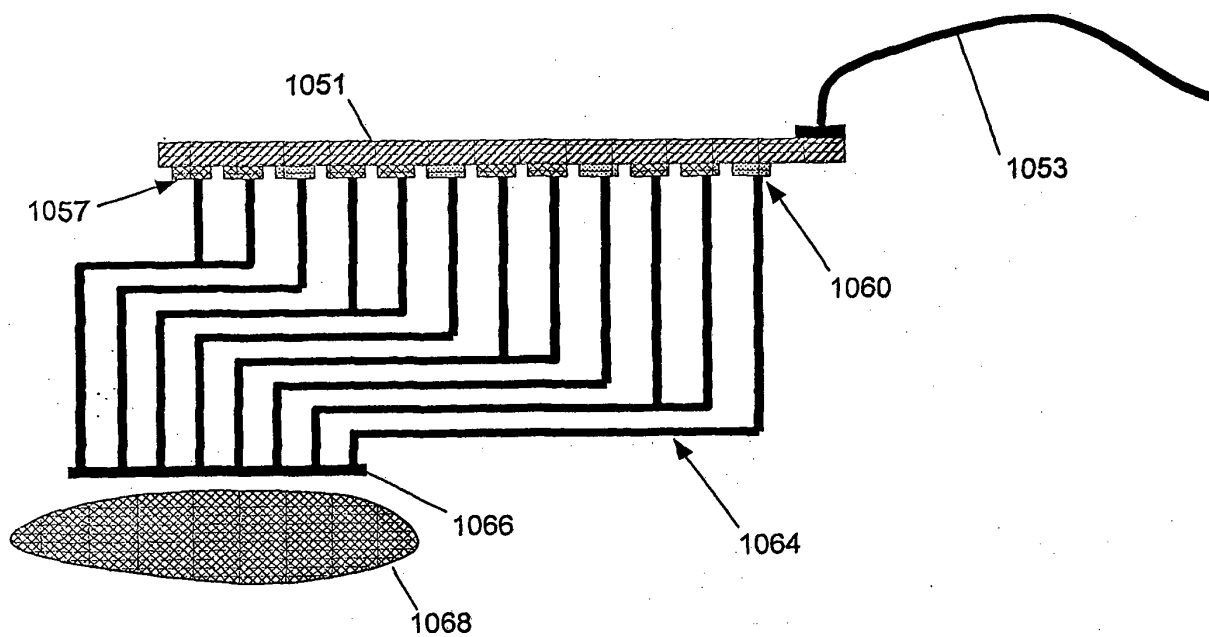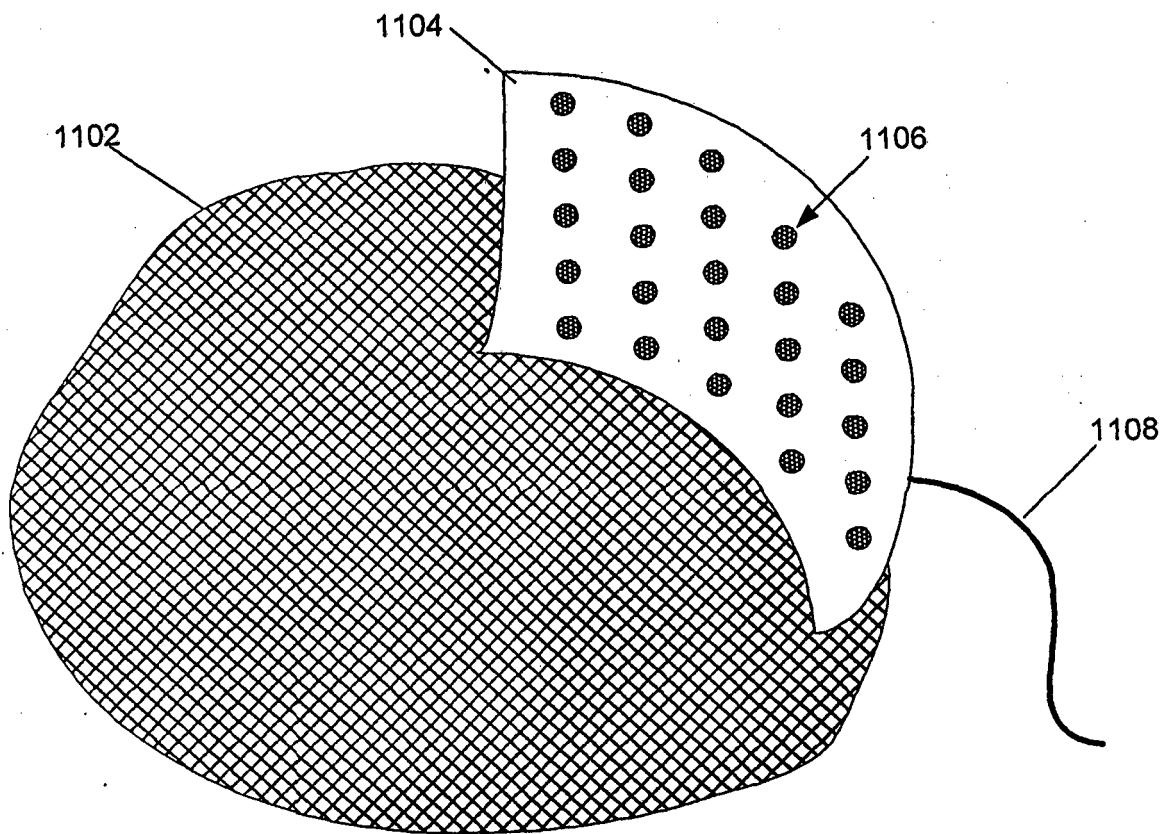
Figure 10c

Figure 11a

Figure 11b
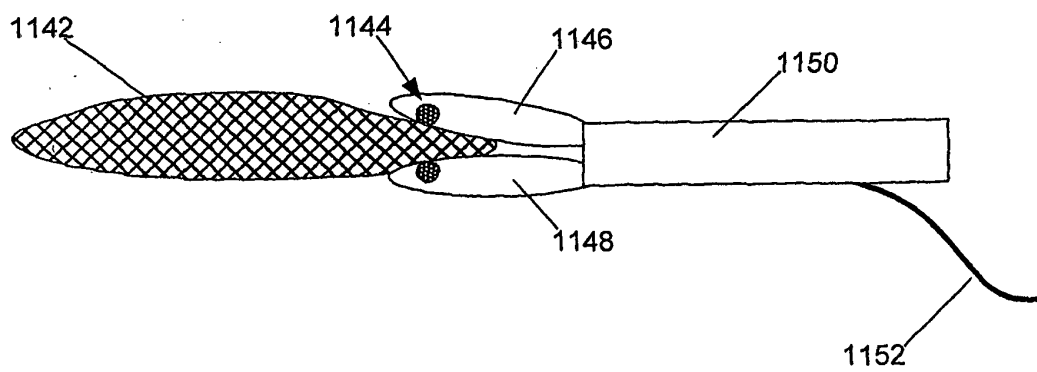
Figure 11c

Figure 11d

Figure 11e

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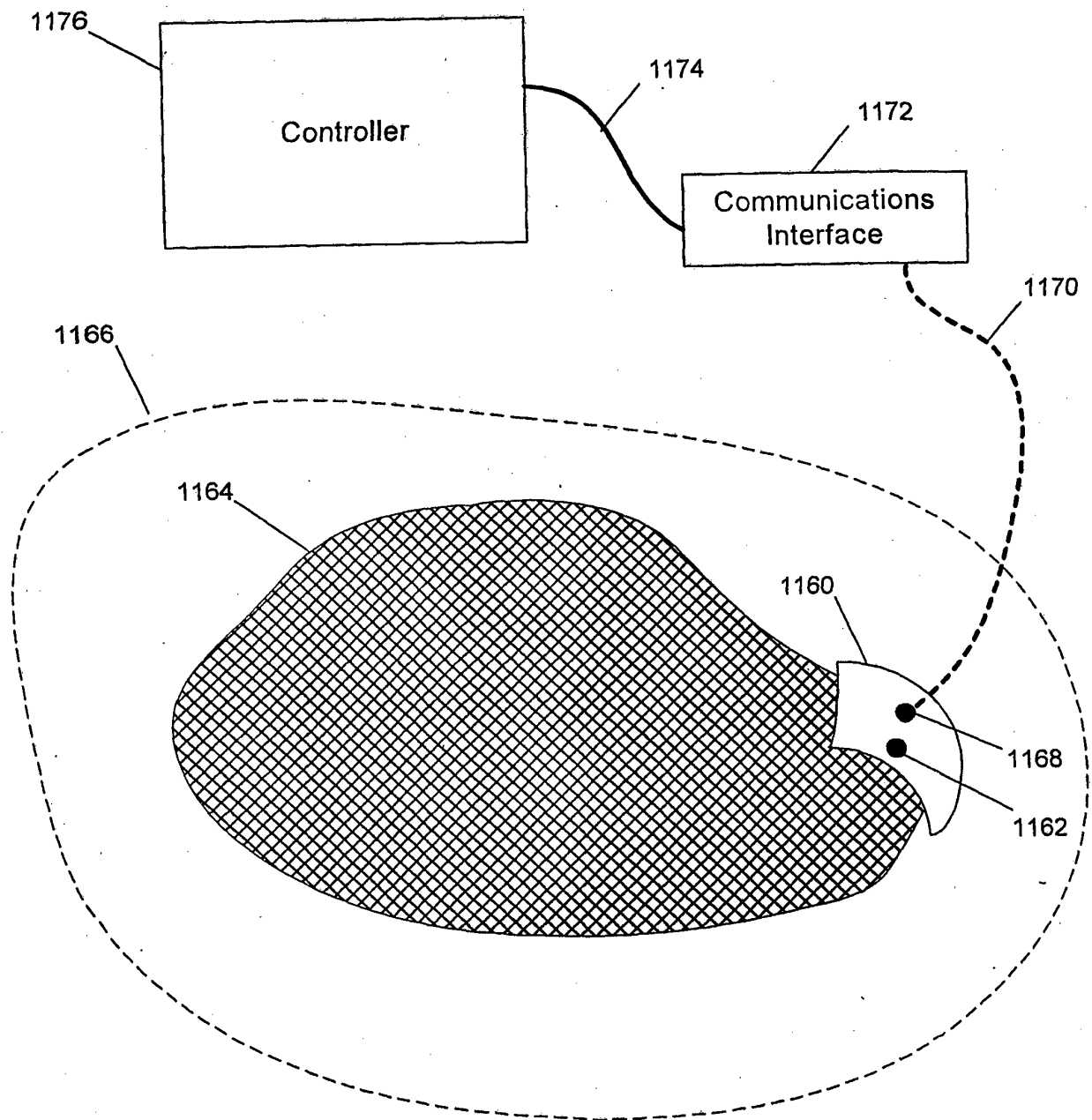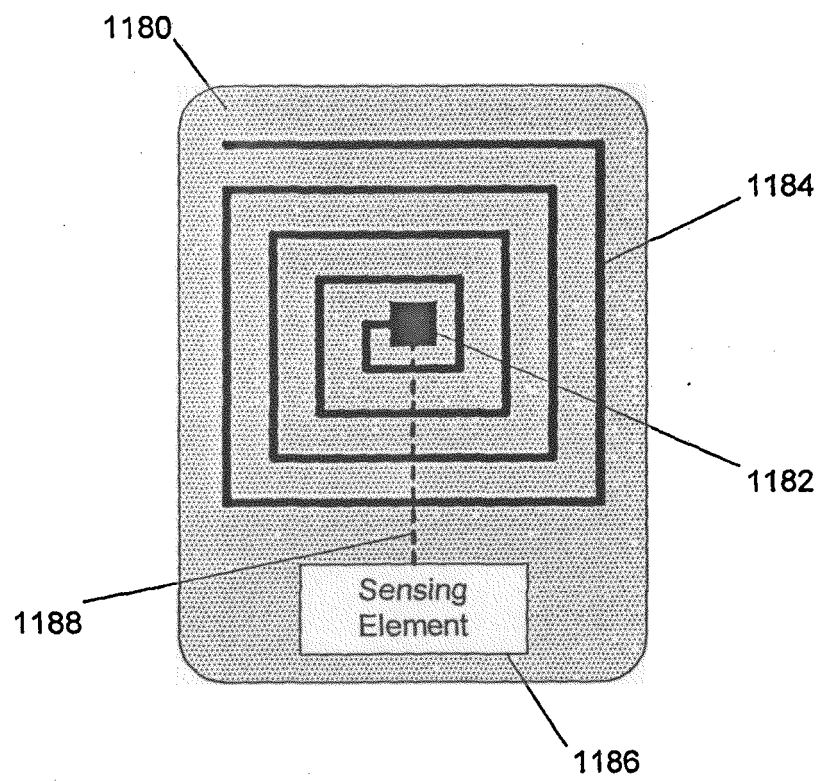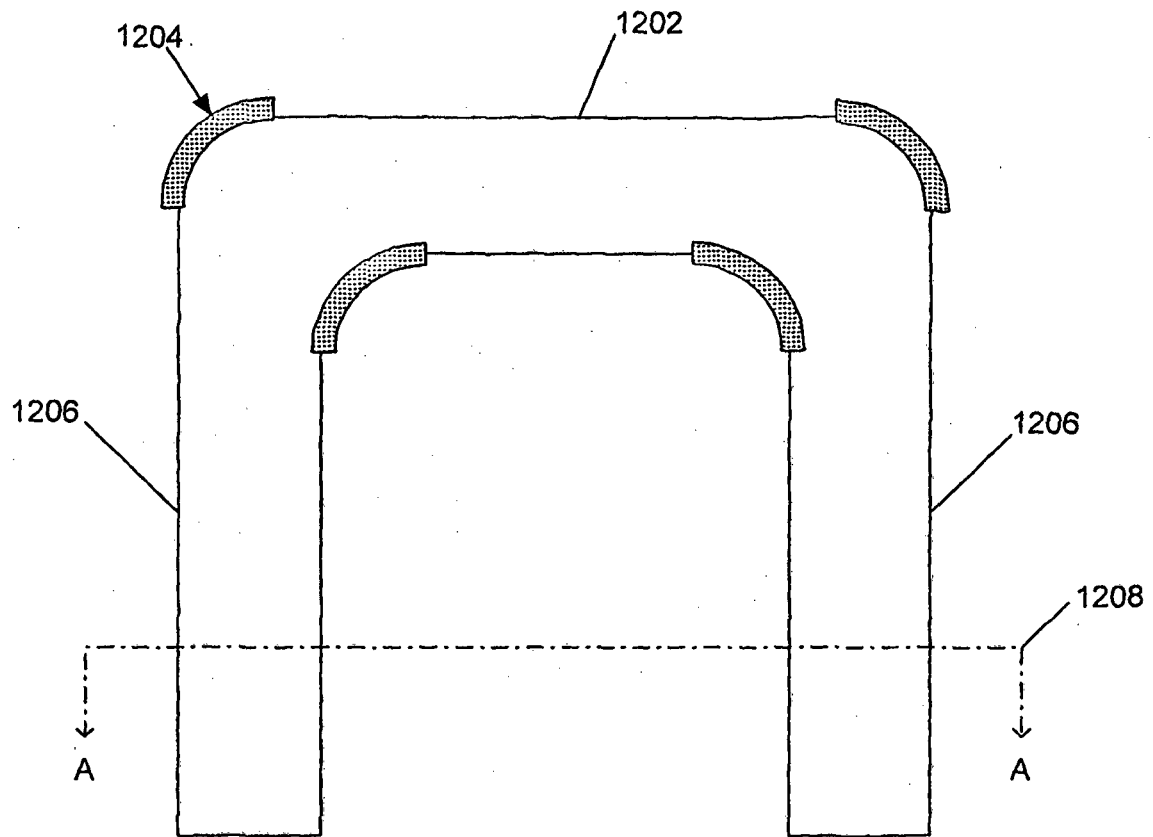
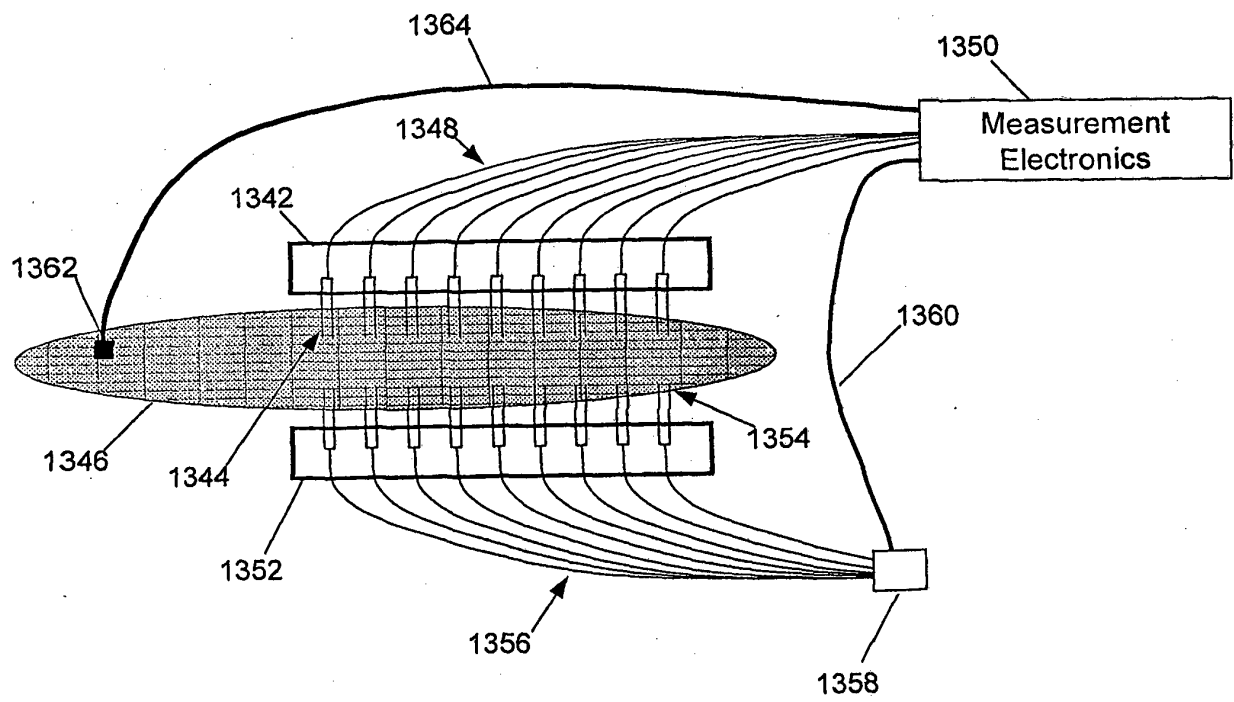Figure 12a

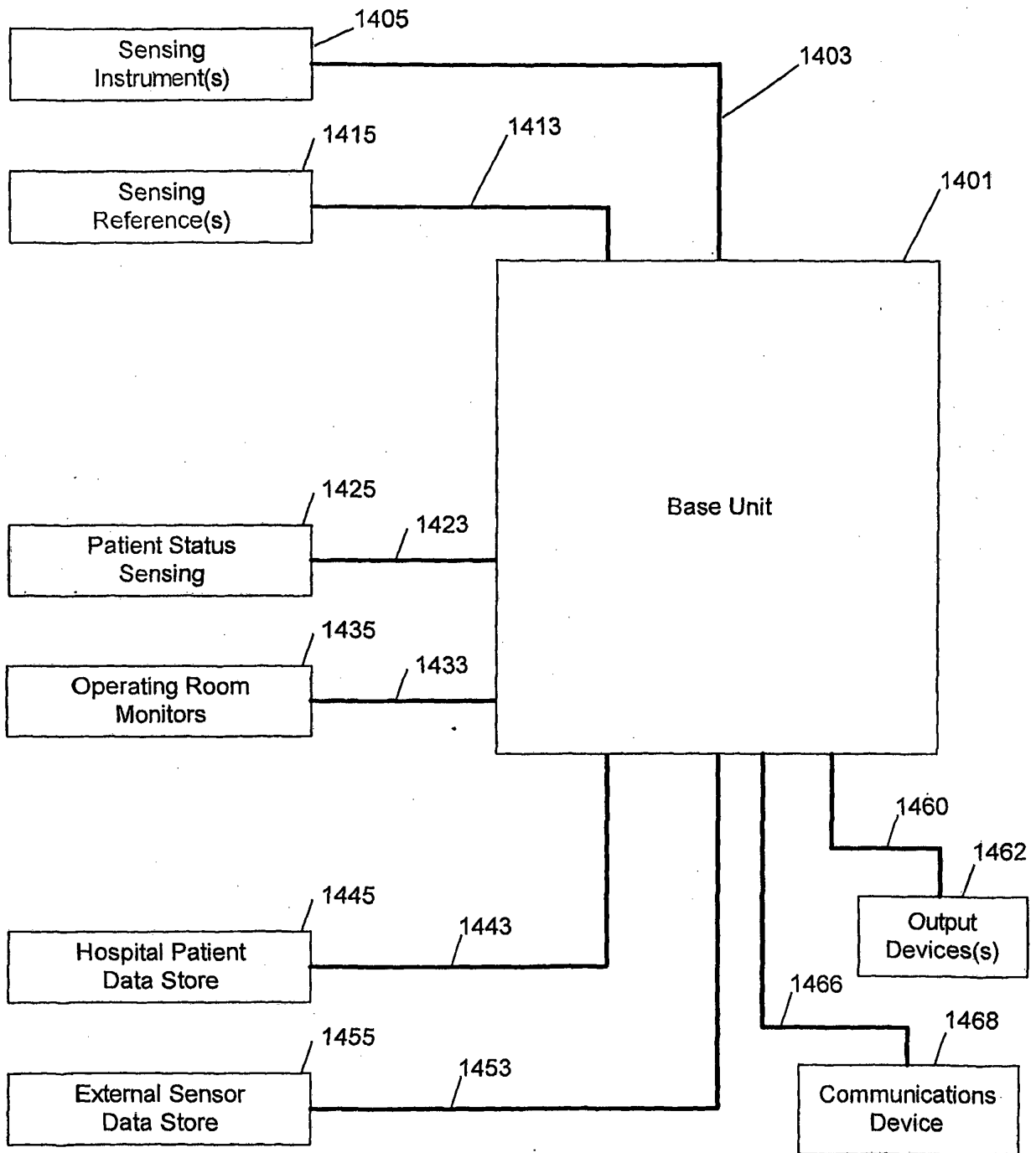Section A-A
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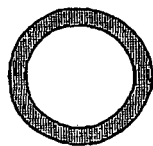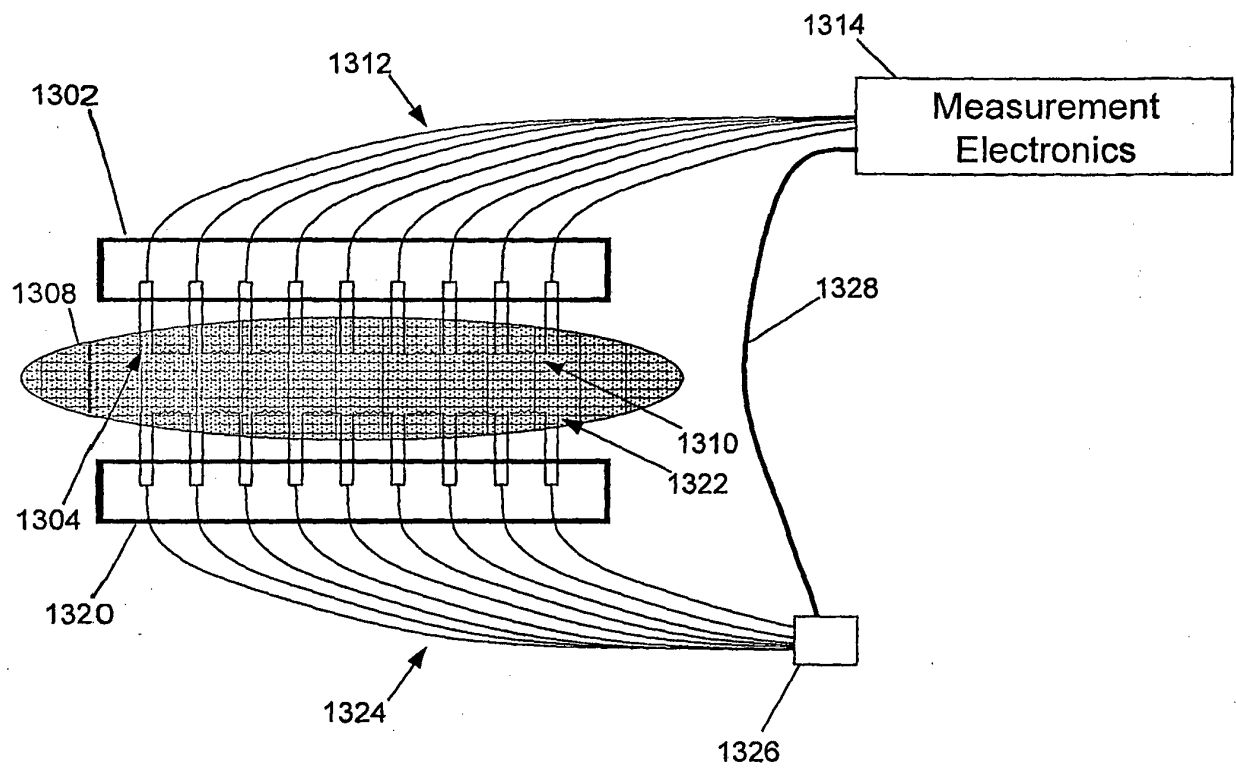
Figure 12b

Figure 13a

Figure 13b

Figure 14

REFERENCES CITED IN THE DESCRIPTION

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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	EP1868485B1	公开(公告)日	2016-06-08
申请号	EP2006758332	申请日	2006-04-14
申请(专利权)人(译)	SURGISENSE CORPORATION		
当前申请(专利权)人(译)	SURGISENSE CORPORATION		
[标]发明人	ZAND JASON MATTHEW FISCHER GREGORY SCOTT		
发明人	ZAND, JASON, MATTHEW FISCHER, GREGORY, SCOTT		
IPC分类号	A61B5/00 A61B17/00 A61M25/00		
CPC分类号	A61B5/0261 A61B5/0071 A61B5/0075 A61B5/0084 A61B5/0086 A61B5/14542 A61B5/1455 A61B5/1459 A61B5/413 A61B5/6837 A61B5/7275 A61B5/7405 A61B5/742 A61B5/7455 A61B17/02 A61B17/0644 A61B17/068 A61B17/07207 A61B17/1155 A61B17/29 A61B34/30 A61B2017/00022 A61B2017/00026 A61B2017/00053 A61B2017/00066 A61B2017/07214 A61B2017/07228 A61B2034/301 A61B2090/064 Y10S901/09 Y10S901/44		
优先权	60/766359 2006-01-12 US 60/671872 2005-04-15 US		
其他公开文献	EP1868485A2 EP1868485A4		
外部链接	Espacenet		

摘要(译)

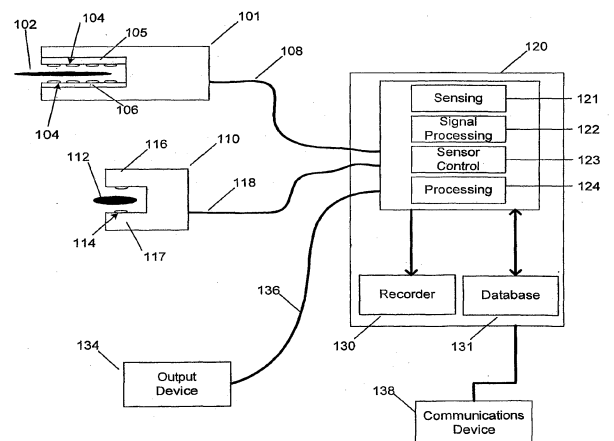本发明涉及一种系统，包括：手术器械，包括入射光源和传感器，用于使用来自光源的入射光产生指示已经引入荧光介质的对象组织的荧光的信号;处理器，被配置为接收信号并响应于信号指示的荧光响应确定受试者组织的组织特征。

Figure 1