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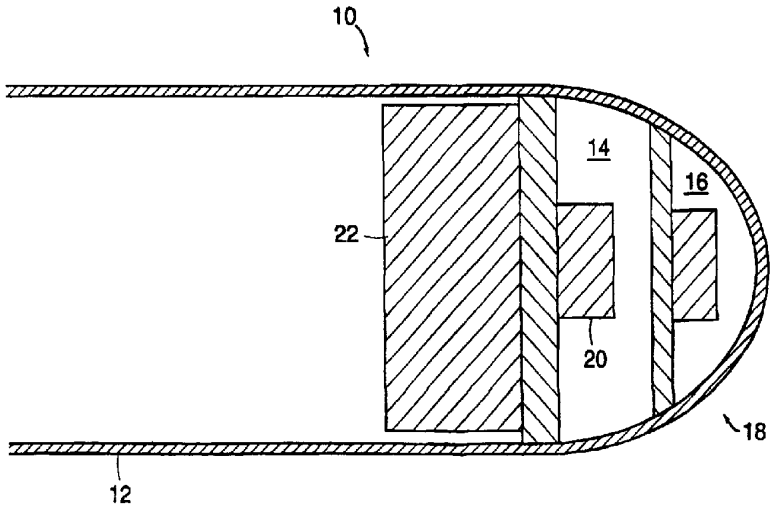

(57) Abstract

A display (14) is located on an interventional device (10) insertible into a body. More specifically, the display (14) is located on a distal end (18) of the device (10) and is coupled to a sensing system (16). The sensing system (16) senses a bodily condition. The display (14) receives the sensed bodily condition and displays a signal indicative of the bodily condition within a pre-existing field of view.

Visible Display for an Interventional Device

Field of the Invention

The invention relates generally to interventional devices for use in a body. More particularly, the invention relates to a visible display located at the distal end of an interventional device for use in a body.

Background of the Invention

Interventional devices are used to perform minimally invasive diagnostic and therapeutic procedures. The interventional device can include, without limitation, a catheter, an endoscope, a guide wire, a needle or an introducer. Endoscopes, for example, provide high-resolution detailed views of internal organs and body cavities. Typically, catheters and other interventional devices are used in conjunction with endoscopes to provide an auxiliary diagnostic or therapeutic capability. Positioning and guidance of the interventional device is accomplished readily by direct observation.

Recently, optical biopsy, ultrasound, and other sensor-based diagnostic devices have been incorporated into the interventional device which is used in conjunction with an endoscope and an auxiliary viewing, analysis or externally indicating console. These devices can include an image overlay, numeric data, or other information needed to quantify or recognize a biological (or morphological) region or condition. Attempts have been made to overlay this information onto existing video displays commonly used with endoscopes to provide an image that is easier to interpret and does not require the switching of display screens or otherwise divert the attention of the doctor to other indicia. Adoption of these displays has been slow, however, due to the need to hardwire attachments and other electronics onto existing devices. The adoption process has been further slowed by the need for extensive testing of these attachments to obtain regulatory approvals.

The reference to any prior art in this specification is not, and should not be taken as, an acknowledgment or any form of suggestion that that prior art forms part of the common general knowledge in Australia.

Summary of the Invention

It is an object of the invention to address or ameliorate one or more of the problems or shortcomings of the prior art.

The present invention provides an interventional device comprising:

an elongated member insertible into a body;

a sensing system disposed in a distal end of the elongated member for sensing a bodily condition; and

a display coupled to the sensing system and distinct therefrom, and located on the distal end of the elongated member for providing a signal indicative of a bodily condition.

The present invention further provides a method for observing a signal indicative of a bodily condition comprising:

inserting an interventional device into a body, the device having a display and a sensor distinct from each other, both located on a distal end of the device;

contacting tissue in the body with the interventional device to sense a bodily condition therefrom; and

viewing a signal indicative of the sensed bodily condition provided by the display.

The present invention further provides a method for displaying a signal indicative of a bodily condition comprising:

inserting an interventional device into a body, the device having a display and a

sensor distinct from each other, both located on a distal end of the device;

manipulating the interventional device to contact a region in the body for sensing a bodily condition therefrom; and

displaying a signal indicative of the sensed bodily condition on the display.

The present invention further provides an interventional device comprising:

an elongated member insertible into a body;

a sensing system disposed in the elongated member at a distal end for sensing a bodily condition, the sensing system including at least one light source and at least one light detector; and

a display located at the distal end of the elongated member for providing a signal indicative of the bodily condition.

The present invention further provides a method for observing a signal indicative of a bodily condition comprising:

inserting an interventional device including a sensing system and a display located at a distal end thereof into a body;

contacting tissue in the body with the interventional device;

illuminating the tissue;

detecting a spectral emission from the illuminated tissue to sense a bodily condition therefrom;

generating a signal indicative of the sensed bodily condition; and

viewing the signal indicative of the sensed bodily condition provided by the display.

The present invention further provides a method for displaying a signal indicative of a bodily condition comprising:

inserting an interventional device comprising a sensing system and a display located at a distal end thereof into a body;

manipulating the interventional device to contact a region in the body;

illuminating the region;

detecting a spectral emission from the illuminated region for sensing a bodily condition therefrom;

generating a signal indicative of the sensed bodily condition; and

displaying the signal indicative of the sensed bodily condition on the display.

In one embodiment, the invention relates to a display located on a distal end of an interventional device. The display includes an indicator for providing a signal indicative of a bodily condition. The indicator provides a visible signal indicative of the bodily condition within a pre-existing field of view of the interventional device or of a remote display system. The indicator can comprise at least one of the following light emitters (a) a light emitting diode, (b) a liquid crystal display, or (c) a projection display. The indicator can also comprises at least one of the following (a) an optical emitter, (b) a chemical indicator, or (c) a polymeric emitter. The chemical indicator can comprise litmus paper, and the polymeric emitter can comprise at least one organic light emitting diode.

In a detailed embodiment, the display can also include a power source and a sensing system located in the distal end of the interventional device. The power source provides power to the display and can be a small battery. The sensing system provides a signal indicative of the sensed bodily condition to the indicator. The sensing system comprises a sensor or a light source in combination with a light detector. The detector is adapted for monitoring light emissions from the light source. A filter can be disposed adjacent the detector for selectively detecting light emissions having a pre-determined wavelength. Multiple batteries, sensors, light sources, light detectors and filters can be used.

In another embodiment, the invention relates to an interventional device comprising an elongated member and a display. The elongated member is insertible into a body for diagnostic and/or therapeutic procedures. A sensing system disposed in the distal end of the elongated member senses a bodily condition. The display is located on a distal end of the elongated member and is coupled to the sensing system for receiving the sensed bodily condition. The display provides a signal indicative of the sensed bodily condition.

The display can include an indicator for providing the signal indicative of the bodily condition within a pre-existing field of view of the interventional device or of a remote display system. The indicator can comprise at least one of the following (a) a light emitter, (b) an optical emitter. (c) a chemical indicator. or (d) a polymeric emitter.

The interventional device can also include a power source and a sensing system located in the distal end of the interventional device. The power source provides power to the display. The sensing system comprises a sensor or a light source in combination with a light detector. A filter disposed adjacent the detector selectively detects light emissions having a pre-determined wavelength. Multiple power sources. sensors. light sources, light detectors and filters can be used.

In yet another embodiment, the invention relates to a method for observing a signal indicative of a bodily condition. An interventional device having a display located on a distal end thereof is inserted into a body. The interventional device contacts tissue in the body to sense a bodily condition therefrom. A signal indicative of the sensed bodily condition can be viewed on the display.

In yet another embodiment, the invention relates to a method for displaying a signal indicative of a bodily condition. An interventional device having a display located on a distal end thereof is inserted into a body. The interventional device is manipulated to contact a region in the body for sensing a bodily condition therefrom. A signal indicative of the sensed bodily condition can be viewed on the display within a pre-existing field of view.

Brief Description of the Drawings

FIG. 1 is a cross-sectional view of an interventional device including a display located at the distal end of the interventional device.

FIG. 2 is a cross-sectional view of an interventional device including a light source, detectors, a display, a signal processor and a power source located at the distal end of the interventional device.

FIG. 3 is a cross-sectional view of an interventional device including electrodes, a display, a signal processor and a power source located at the distal end of the interventional device.

FIGS. 4 is a graph illustrating the fluorescence spectrum for normal and cancerous bladder tissue.

FIGS. 5A and 5B are illustrations of the display located at the distal end of an interventional device for cancerous and normal colon tissue.

Detailed Description

Referring to FIG. 1, an interventional device 10 includes an elongated member 12 and a display 14. The elongated member 12 can be inserted into a body for diagnostic and/or therapeutic procedures. The display 14 is located at the distal end of the elongated member 12. A sensing system 16, which is also located the distal end 18 of the elongated member 12, senses a bodily condition. The display 14 receives the sensed bodily condition from the sensing system 16 and displays a signal indicative of the sensed bodily condition.

More specifically, the display 14 includes an indicator 20 that provides a visible signal indicative of the bodily condition within a pre-existing field of view of the interventional device or of a remote display system. The indicator 20 can comprise at least one of the following: (a) light emitters (e.g., a light emitting diode, a liquid crystal display or a multi-color display); (b) an optical emitter, (b) a chemical indicator (e.g., litmus paper); or (c) a polymeric emitter (e.g., an organic light emitting diode). The indicator 20 can indicate states, such as ON or OFF, a numeral, letter, shape or image. In addition, the indicator 20 be a projection display that projects indicia upon the interventional device or on tissue. A projection display can include a light emitter focused by a lens and scanned with a 2-axis piezoelectric scanner. Other types of projection displays, which are known in the art, can be used.

The interventional device can also include a power source 22 in the distal end of the interventional device. The power source 22 provides power to the display 14 and can be a small battery.

In one embodiment, the sensing system 16 can comprises a sensor or a light source in combination with a light detector. The detector is adapted for monitoring light emissions from the light source. In another embodiment, the sensing system 16 can comprises a sensor which when disposed in close proximity to a changed bodily condition, varies the power source 22 and provide a signal to the display 14. The sensor can be an arrangement of electrodes which allows current to flow from a separate source (e.g., a battery) when the electrodes are placed in a conductive fluid (e.g., saline). The current passed can also power a small light bulb to indicate to the user that the electrodes are in good contact with the tissue under examination. In yet another embodiment, the sensing system 16 can be a fluorescence detection system. Such a system is described in commonly owned U.S. patent number 6,119,031, entitled, "Miniature Spectrometer" by Robert J. Crowley, which description is incorporated herein by reference. In another embodiment, an impedance sensing system, which is used with certain RF ablation techniques, can be employed. In these techniques, tissue to be destroyed by the application of RF energy may be subject to charring or incomplete ablation if certain electrical contact conditions, such as the resistance of an electrode in contact with tissue, exist. Such conditions can be monitored and displayed on the display 14. In yet another embodiment, chemical specific sensors can be used. Such sensors can be electronically coupled to the display or can be a simple chemical indicator such as litmus paper. The electrical (chemical) sensors may have receptor channels upon which specific molecules are known to preferentially adhere. Sufficient molecules in an area of these sensors may accumulate to cause a change in the electrical resistance of the sensor, and such change can be quickly, efficiently and inexpensively be displayed on the display.

Referring to FIG. 2, an interventional device 30 includes an elongated member 32 insertible into a body (not shown) for diagnostic and/or therapeutic procedures. A display 34 is mounted onto a mounting structure 36 at the distal end of the elongated member 32. The display 34 includes a pair of light emitting diodes (LEDs) 38a, 38b for providing a visible signal indicative of the bodily condition within a pre-existing field of view. The LEDs 38a, 38b are electrically connected to a signal processor 40 via electrical lines 42. A power source 44 provides power to the display via an electrical contact 46, the signal processor 40 and electrical lines 41, 42. The power source 44 is located adjacent a mounting structure 48 and secured by a ground spring 50. The sensing system 52 is mounted to a mounting structure 53 at the distal end of the

interventional device 30 and comprises an LED 54 and a pair of detectors 56a, 56b. Filters 58a, 58b can be disposed adjacent the detectors 56a, 56b.

In operation, the LED 54 emits light that impinges upon tissue under examination. The detectors 56a, 56b in combination with the filters 58a, 58b selectively detecting spectral emissions (e.g., fluorescence emitted by the tissue with a pre-determined wavelength range. The detectors 56a, 56b are electrically connected to the processor 40 via the signal line 60. In response to the signals received from the detectors 56a, 56b, the processor 40 provides a signal indicative of a bodily condition to one of the LEDs 38a, 38b. One of the LEDs turns ON to provide an indication of the sensed bodily condition. The distal end of the intervention device is at least semi-transparent, thereby allowing the user to readily observe the activated LED.

Referring to FIG. 3, an interventional device 70 includes an electrode-based sensing system. The sensing system 72 includes a pair of electrodes 74a, 74b mounted at the distal end of the interventional device 70 for sensing a bodily condition. In operation, the electrodes 74a, 74b a bodily condition and provide corresponding signals to the processor 40 via signal lines 76. In response to the signals received from the sensors 74a, 74b, the processor 40 provides a signal indicative of a bodily condition to one of the LEDs 38a, 38b. One of the LEDs turns ON to display an indication of the sensed bodily condition.

FIG. 4 is a graph illustrating the fluorescence spectrum for normal and cancerous bladder tissue. An excitation wavelength of around 300 nanometers is used to excited suspicious bladder tissue. The resulting tissue fluorescence curves for normal tissue 80 and cancerous tissue 82 is shown. For normal tissue, a peak exists in the 440 to 460 nanometer range. For cancerous tissue, a peak exists in the 370 nanometer range. Both of these spectral responses are in the ultraviolet or blue range of the frequency spectrum and may not be readily visible to the human eye, which has limited sensitivity below 400 nanometers.

FIGS. 5A and 5B are illustrations of the display located at the distal end of an interventional device for cancerous and normal colon tissue. Referring to FIG. 5A, an interventional device 90 is positioned adjacent tissue 92. The device 90 includes a display 94 having a first color and a second color, both of which can be visible to the human eye. The display can include a pair of LEDs. The sensing system (not shown) senses a bodily condition. In response to the sensed bodily condition, the display 94 generates the first color to indicate

cancerous tissue. Referring to FIG. 5B, the interventional device 90 is positioned adjacent tissue 96. The sensing system (not shown) senses a bodily condition. In response to the sensed bodily condition, the display generates the second colour to indicate normal tissue.

Equivalents

Variations, modifications, and other implementations of what is described herein will occur to those of ordinary skill in the art without departing from the spirit and scope of the invention as claimed. Accordingly, the invention is to be defined not by the preceding illustrative description but instead by the spirit and scope of the following claims.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. An interventional device comprising:

an elongated member insertible into a body;

a sensing system disposed in a distal end of the elongated member for sensing a bodily condition; and

a display coupled to the sensing system and distinct therefrom, and located on the distal end of the elongated member for providing a signal indicative of a bodily condition.

2. The interventional device of claim 1 wherein the display further comprises an indicator which provides a visible signal indicative of a bodily condition.

3. The interventional device of claim 2 wherein the indicator comprises at least one light emitter.

4. The interventional device of claim 3 wherein at least one of the light emitters comprises (a) a light emitting diode, (b) a liquid crystal display, or (c) a projection display.

5. The interventional device of claim 2 wherein the indicator comprises at least one optical emitter.

6. The interventional device of claim 2 wherein the indicator comprises at least one chemical indicator.

7. The interventional device of claim 6 wherein at least one of the chemical indicators comprises litmus paper.

8. The interventional device of claim 2 wherein the indicator comprises at least one polymeric emitter.

9. The interventional device of claim 8 wherein at least one of the polymeric emitters

comprises at least one organic light emitting diode.

10. The interventional device of claim 1 further comprising:
a power source for providing power to the display.

11. The interventional device of claim 10 wherein the display receives the sensed bodily condition from the sensing system and provides a visible signal indicative of the sensed bodily condition.

12. The interventional device of claim 10 wherein the sensing system comprises at least one sensor.

13. The interventional device of claim 12 wherein at least one of the sensors comprises an electrode.

14. The interventional device of claim 12 wherein the sensing system comprises at least one light source and at least one detector.

15. The interventional device of claim 14 wherein at least one of the detectors is adapted for monitoring light emission from at least one of the light sources.

16. The interventional device of claim 15 further comprising at least one filter disposed adjacent at least one of the detectors for selectively detecting light emission having a pre-determined wavelength.

17. The interventional device of claim 1 wherein the display provides a visible signal indicative of the bodily condition within a pre-existing field of view.

18. A method for observing a signal indicative of a bodily condition comprising:

inserting an interventional device into a body, the device having a display and a sensor distinct from each other, both located on a distal end of the device;

contacting tissue in the body with the interventional device to sense a bodily condition therefrom; and

viewing a signal indicative of the sensed bodily condition provided by the display.

19. The method of claim 18 further comprising providing a sensing system disposed in the distal end of the interventional device for sensing the bodily condition.

20. The method of claim 18 further comprising providing a visible signal indicative of the bodily condition within a pre-existing field of view.

21. A method for displaying a signal indicative of a bodily condition comprising:

inserting an interventional device into a body, the device having a display and a sensor distinct from each other, both located on a distal end of the device;

manipulating the interventional device to contact a region in the body for sensing a bodily condition therefrom; and

displaying a signal indicative of the sensed bodily condition on the display.

22. An interventional device comprising:

an elongated member insertible into a body;

a sensing system disposed in the elongated member at a distal end for sensing a bodily condition, the sensing system including at least one light source and at least one light detector; and

a display located at the distal end of the elongated member for providing a signal indicative of the bodily condition.

23. The interventional device of claim 22 wherein the display further comprises an indicator which provides a visible signal indicative of a bodily condition.

24. The interventional device of claim 23 wherein the indicator comprises at least one light emitter.

25. The interventional device of claim 24 wherein the at least one light emitter comprises (a) a light emitting diode, (b) a liquid crystal display, or (c) a projection display.

26. The interventional device of claim 23 wherein the indicator comprises at least one optical emitter.

27. The interventional device of claim 23 wherein the indicator comprises at least one chemical indicator.

28. The interventional device of claim 27 wherein the at least one chemical indicator comprises a litmus paper.

29. The interventional device of claim 23 wherein the indicator comprises at least one polymeric emitter.

30. The interventional device of claim 29 wherein at least one of the polymeric emitters comprises at least one organic light emitting diode.

31. The interventional device of claim 22 further comprising a power source for providing power to the display.

32. The interventional device of claim 31 wherein the display receives the sensed bodily condition from the sensing system and provides a visible signal indicative of the sensed bodily condition.

33. The interventional device of claim 31 wherein the sensing system comprises at least one sensor.

34. The interventional device of claim 33 wherein the at least one sensor comprises an electrode.

35. The interventional device of claim 22 wherein the at least one light detector is adapted for monitoring light emission from at least one light source.

36. The interventional device of claim 35 further comprising at least one filter disposed adjacent the at least one detector for selectively detecting light emission having a pre-determined wavelength.

37. The interventional device of claim 22 wherein the display provides a visible signal indicative of the bodily condition within a pre-existing field of view.

38. The interventional device of claim 22, wherein the display is coupled to the sensing system for receiving the signal indicative of the bodily condition and providing a visible signal indicative of the bodily condition within a pre-existing field of view.

39. A method for observing a signal indicative of a bodily condition comprising:

inserting an interventional device including a sensing system and a display located at a distal end thereof into a body;

contacting tissue in the body with the interventional device;

illuminating the tissue;

detecting a spectral emission from the illuminated tissue to sense a bodily condition therefrom;

generating a signal indicative of the sensed bodily condition; and

viewing the signal indicative of the sensed bodily condition provided by the display.

40. The method of claim 39 further comprising providing a sensing system disposed in the distal end of the interventional device for sensing the bodily condition.

41. The method of claim 39 further comprising providing a visible signal indicative of the bodily condition within a pre-existing field of view.

42. A method for displaying a signal indicative of a bodily condition comprising:

inserting an interventional device comprising a sensing system and a display located at a distal end thereof into a body;

manipulating the interventional device to contact a region in the body;

illuminating the region;

detecting a spectral emission from the illuminated region for sensing a bodily condition therefrom;

generating a signal indicative of the sensed bodily condition; and

displaying the signal indicative of the sensed bodily condition on the display.

43. An interventional device substantially as hereinbefore described with reference to the accompanying drawings.

44. A method for observing a signal indicative of a bodily condition substantially as hereinbefore described with reference to the accompanying drawings.

45. A method for displaying a signal indicative of a bodily condition substantially as hereinbefore described with reference to the accompanying drawings.

DATED this 25th day of October, 2002

Boston Scientific Limited

by DAVIES COLLISON CAVE
Patent Attorneys for the Applicant

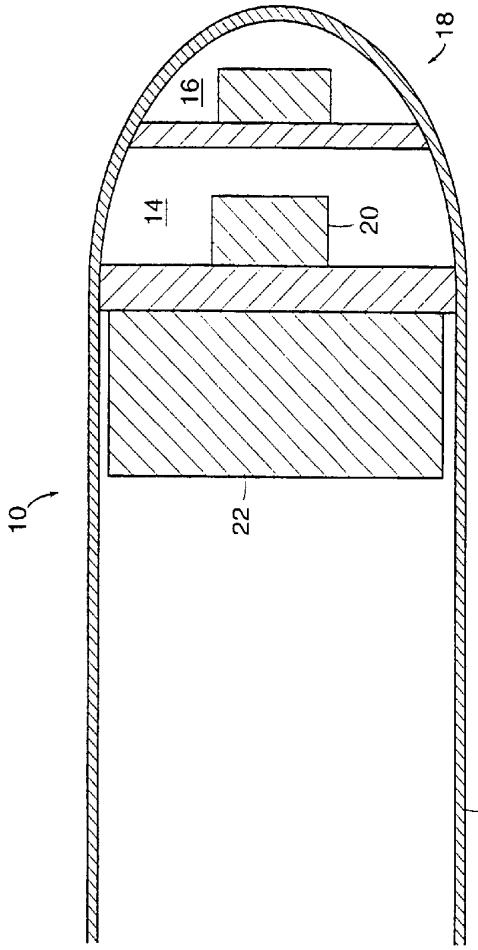

FIG. 1

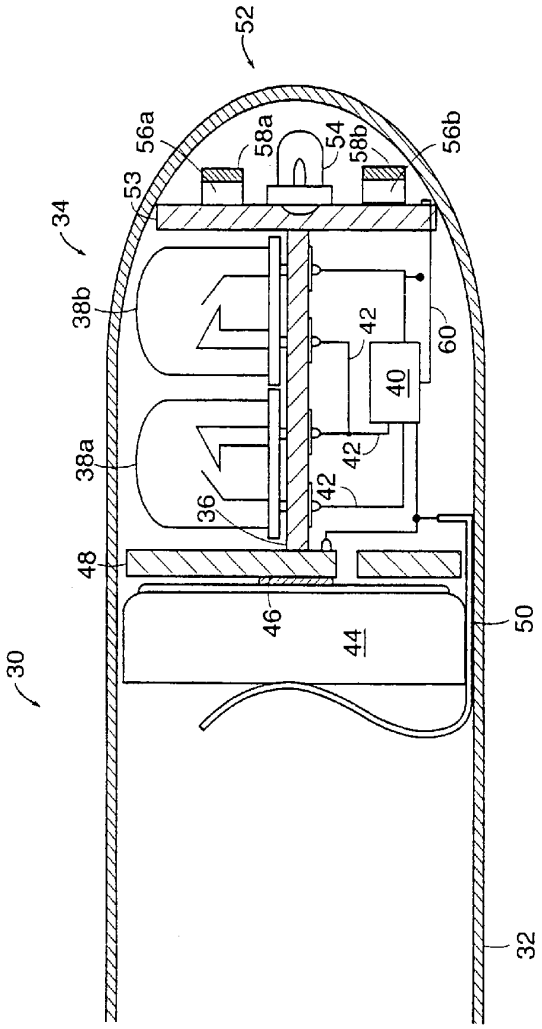
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FIG. 2

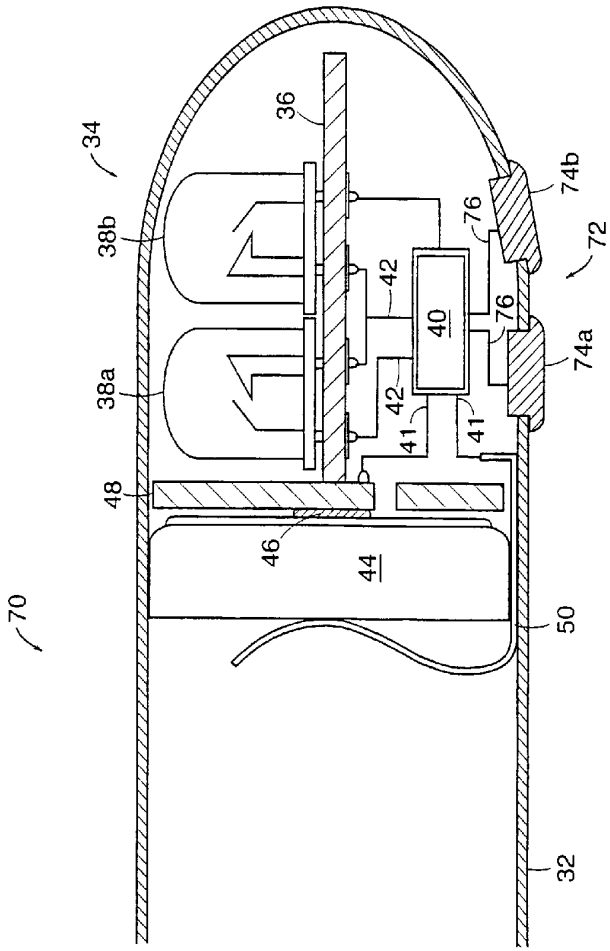
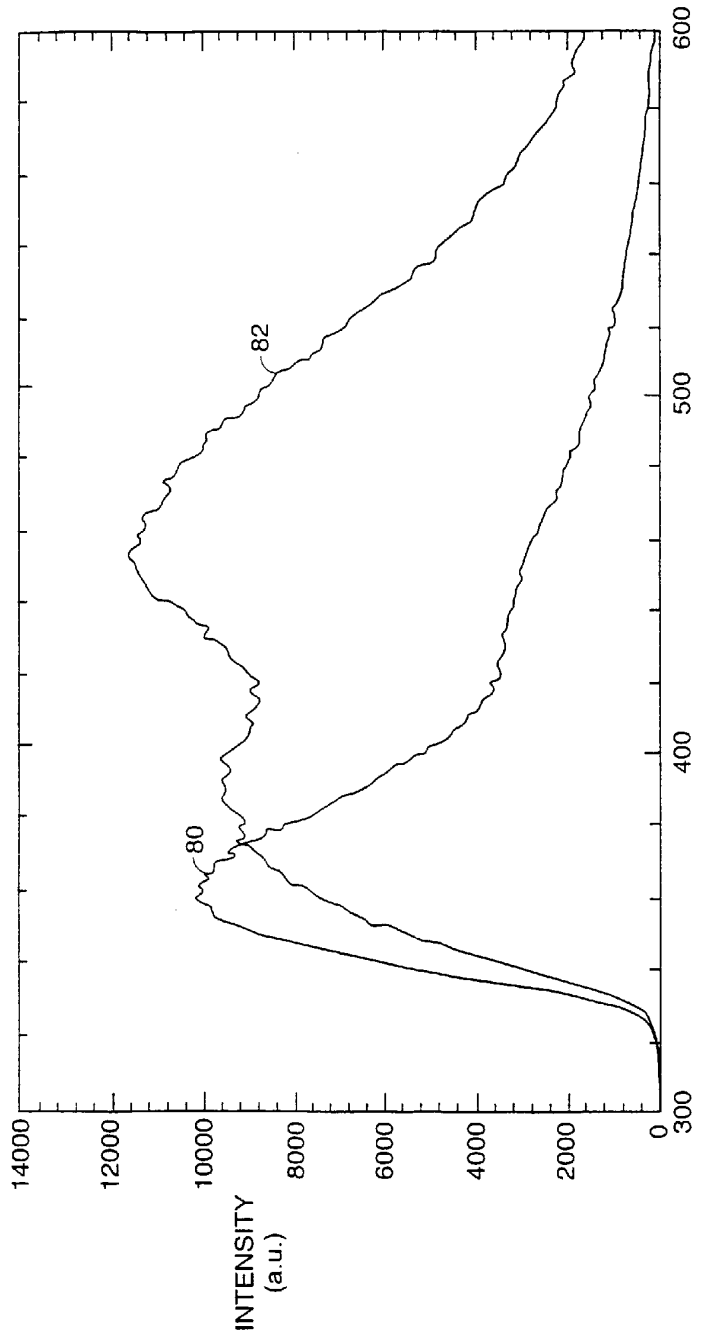


FIG. 3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400
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FIG. 4

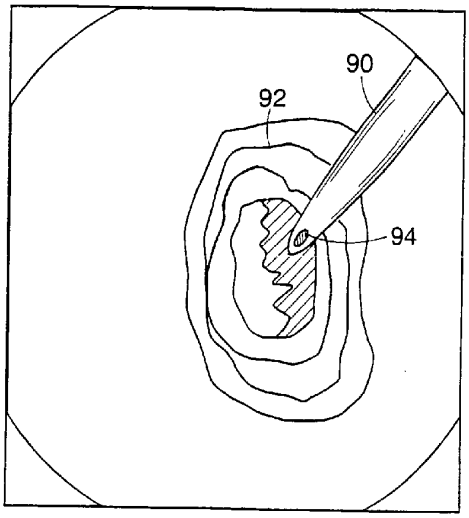

FIG. 5A

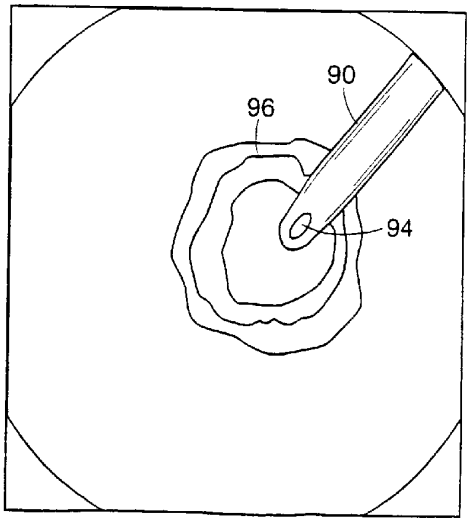

FIG. 5B