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(57) Abstract: A system and method may provide treatment of an in vivo site, for example, using an in vivo imaging device such as an immobilized imaging device, a receiver and a generator, for example an ultrasound generator, an electro-magnetic energy generator or a radiation generator.

METHOD AND SYSTEM FOR TREATMENT OF AN IN VIVO SITE

FIELD OF THE INVENTION

The present invention relates to the field of therapeutics. More specifically,
5 the present invention relates to an in-vivo sensing device, system and method for
determining the location of an in vivo site for directing therapeutics to that site.

BACKGROUND OF THE INVENTION

It is possible to immobilize a sensing device in-vivo for continuous
monitoring of an in-vivo site. For example, a pH meter can be immobilized to the
10 inside of a patient's esophagus to monitor the pH of the environment, for example,
to check for Gastro Esophageal Reflux Disease (GERD). In the course of
treatment of an in-vivo condition, such as for example a cancerous growth, a
gallstone or other pathological condition, it is sometimes desirable to view changes
in size, color or other conditions of an in-vivo object being treated. An
15 immobilizable in vivo imaging device may be useful for such monitoring.

Although monitoring may be an important aspect of therapy, monitoring
methods alone may not be sufficient to provide treatment to a pathological
condition.

SUMMARY OF THE INVENTION

20 Some embodiments of the invention may provide a device, system and
method for treating an in vivo pathology. Embodiments of the invention may
include a system and method for determining the distance and direction from,
for example, an irradiating generator to an in-vivo object or location. Such
embodiments may include the determination of the distance vectors from an
25 imaging device, for example, to an in-vivo object and from the imaging device to
a generator, in order to calculate the distance and/or direction from the
irradiating generator to the in-vivo object.

According to some embodiments of the invention treatment of in vivo
pathologies, such as polyps in the GI tract, may be focused and localized,
30 avoiding the need to, for example, unnecessarily treat a large area. For

avoiding the need to, for example, unnecessarily treat a large area. For example, according to an embodiment of the invention, radiation treatment may be administered locally and focused on a restricted known in vivo area instead of systemic radiation procedures practiced to date.

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BRIEF DESCRIPTION OF THE FIGURES

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the figures in which:

Figure 1 is a flow chart diagram of a method in accordance with an embodiment of the invention;

Figure 2 is a schematic illustration of an embodiment of an immobilizable in-vivo imager system with distance determining capabilities; and

Figure 3 is a flow chart diagram of a method in accordance with an embodiment of the invention.

It will be appreciated that for simplicity and clarity of illustration, elements shown in the figures have not necessarily been drawn to scale. For example, the dimensions of some of the elements may be exaggerated relative to other elements for purposes of clarity.

DETAILED DESCRIPTION OF THE INVENTION

In the following detailed description, numerous specific details are set forth in order to provide a thorough understanding of the invention. However, it will be understood by those skilled in the art that the present invention may be practiced
5 without these specific details. In other instances, well-known methods, procedures, and components have not been described in detail so as not to obscure the present invention.

According to an embodiment of the present invention there is provided a device, system and method for locating a site of interest within a body lumen (or
10 other in vivo site) and directing to the site therapeutics, such as energy for example radiation etc. Embodiments of the invention may utilize immobilizing, affixing or adhering an in-vivo sensing device including for example an imager to an in-vivo site and focusing such imager on a site to be monitored and/or treated.

According to some embodiments of the present invention the system may
15 include a sensing device, a transmitter that transmits the output of the sensing device, a reception system for receiving the transmitted output and a power source, which provides power to the elements of the system. According to one embodiment of the present invention, the sensing device may be connected to or included within a housing (directly or indirectly, e.g., via other elements), which is
20 configured for being transiently or temporarily immobilized in the vicinity of an in vivo site for example, a surgery site. The sensing device may be any device that is adapted for being placed in-vivo, for example, along the GI tract, that may sense environment conditions such as the presence of blood, pH, temperature, electrical impedance of tissues etc., and that may transmit (such as by radio) output relating
25 to changes in the environment conditions. According to one embodiment the sensor may be disposed within the housing. According to one embodiment the device may include an imaging unit.

According to one embodiment the imaging unit may typically include at least one illumination source such as a white LED (light emitting diode) and an
30 imaging device such as a CCD or CMOS image sensor. The imaging system may further include an optical system for imaging an area of interest onto the imaging system. The optical system may include mirrors and/or lenses for collimating the

light from the illumination source. In accordance with this embodiment a reception system may receive for example a transmitted image output and may include an antenna array capable of surrounding a body for receiving the transmitted image output and for producing a plurality of received signals and/or a demodulator
5 capable of transforming the plurality of received signals into, for example, a single image data stream. Optionally the reception system may include a display, such as an LCD, for displaying the data transmitted to it. According to some embodiments, an in vivo imaging device may be self contained and autonomous.

For example, embodiments described in US 5,604,531 or in US Patent
10 Application Number 09/800,470 filed March 8, 2001, may be used with an embodiment of the present invention. US 5,604,531, and US Patent Application Number 09/800,470 are assigned to the common assignee of the present invention and are hereby incorporated by reference.

According to some embodiments of the present invention, all of the
15 components may be sealed within the device body (the body or shell may include more than one piece); for example, the imaging device, illumination units, power units, and transmitting and control units, may all be sealed within the device body.

According to embodiments of the present invention the imaging system may provide direct visual information of the in-vivo site (e.g., a surgical site) such
20 that visibly detectable changes at the site, such as bleeding, swelling etc. can be seen by an external operator. The imaging system may further include a detector coupled to the imaging device that may be optically changed in response to changes in environmental conditions. The optical change in the detector may be imaged and transmitted to a receiving system and may be shown on a display of
25 the receiving unit to alert an external operator of the changed conditions. For example, the imaging system may include a pH meter that undergoes a color change in response to pH changes in its vicinity. According to some embodiments, the imaging system may include a detector of chemical substances, such as blood components, which undergoes a change in color in response to the presence of
30 the chemical substances. In both cases a change in color may be detected by the imaging device and is transmitted and received by the reception system for the inspection of an external operator.

According to some embodiments of the present invention, the sensing device, such as an imaging system, may further be in communication with a processor or control unit for analyzing the data detected by it and possibly for controlling the sensing device. For example, images of a surgical site may be transmitted to a processor where they are analyzed for the presence and possibly the concentration of blood and/or for the presence of pathologies such as growths in the GI tract (for example, by detecting certain changes in color). The image may then be received by the external operator including additional information, generated by the processor, regarding the bleeding at the surgical site. Further, the system may include components for alerting the external operator. The components for alerting the external operator may be in communication with the processor. Thus, when the presence of pathology is detected by the processor a signal, such as a flashing light or an alarm, may be activated to alert the external operator.

The housing of the device, according to an embodiment of the invention, may be configured for being immobilized in the vicinity of an in-vivo site. Some immobilizable housings that may be utilized in the present invention are described in US Patent Application Number 09/963,950 filed on September 26, 2001, which application is assigned to the assignee of the present invention and which application is hereby incorporated by reference in its entirety.

Other exemplary embodiments of immobilizable imaging devices are shown in US Patent Application Number 60/533,264 filed on December 31, 2003, which application is assigned to the assignee of the present invention and which application is hereby incorporated by reference in its entirety.

Reference is made to Fig. 1, a flow chart of a method in accordance with an embodiment of the invention. According to one embodiment of the present invention, in block 100 a housing containing for example an imaging device may be immobilized on or against an endo-luminal wall or other in-vivo surface. According to some embodiments of the present invention, the device may include an imaging sensor or other monitor capable of monitoring an in-vivo area to be monitored and an immobilization unit such as for example rotatable clasps, a suture through a channel, a glue tube, vacuum pad, pin, screw, etc.

In some embodiments, a housing of a device may be positioned or secured against an endo-luminal surface so that an imaging sensor of the device is at an acute angle relative to an endo-luminal wall against which such housing is immobilized. Such positioning may enable the image sensor to capture images of an area to be monitored that is for example on an opposing endo-luminal wall from such point of immobilization.

According to one embodiment of the present invention, in block 102, an imaging device may be focused on a site or in-vivo area to be monitored. Focusing may be performed for example by an external operator by way of for example an endoscope. According to some embodiments of the present invention, a focusing mechanism may be adjusted or moved. According to one embodiment of the present invention, an imaging device may include a focusing mechanism in the form of for example a cam or screw that may be rotated, compressed or otherwise adjusted to alter the position of an imaging sensor relative to the position of a lens, or to otherwise increase or decrease the distance between an imaging sensor and a lens, to focus the image.

According to one embodiment of the present invention, in block 104, image data (or other sensed data) which is typically transmitted wirelessly, is received by an external operator where the data may be analyzed for the presence of pathology and/or for the condition of such pathology.

According to one embodiment of the present invention, in block 106 the distance from the imaging device to a sight of interest (e.g., site of pathology) may be calculated. Additionally the orientation of the imaging device in relation to the site may be determined. According to some embodiments of the present invention, an external therapeutic device (such as a radiation generator) may be positioned outside a patient's body at a known distance and/or orientation from the patient's body. The distance of the therapeutic device from the imaging device may be calculated.

According to one embodiment of the present invention, in block 110 the distance information (and possibly orientation information) may be used to target a treatment (e.g., radiation treatment) at the site.

Fig. 2 describes an in-vivo imager system according to an embodiment of the present invention. According to some embodiments, the in-vivo portion is immobilizable and may include distance and/or orientation determining capabilities. An embodiment of the present invention, as shown in Fig. 2, may include, for example an immobilizable in-vivo imaging device 210, a receiver 200, and a generator 205. According to some embodiments of the present invention, outside a patient's body may be, for example, a receiver 200 (including, for example, an antenna or an antenna array), a storage unit 290, a processor 291, and a monitor 292.

According to some embodiments of the present invention, device 210 typically may be or may include an autonomous swallowable capsule, but device 210 may have other shapes and need not be swallowable or autonomous. Embodiments of device 210 are typically autonomous, and are typically self-contained. For example, device 210 may be a capsule or other unit where all the components are substantially contained within a container or shell, and where device 210 does not require any wires or cables to, for example, receive power or transmit information. Device 210 may communicate with an external receiving and display system to provide display of data, control, or other functions. For example, power may be provided by an internal battery or a wireless receiving system. Other embodiments may have other configurations and capabilities. For example, components may be distributed over multiple sites or units. Control information may be received from an external source.

According to one embodiment of the present invention, the imaging device 210 may include a moveable or otherwise adjustable focusing mechanism. Device 210 may include a container, housing or body 212 which may include for example an optical dome or window 214, behind or adjacent to which may be positioned illumination sources 216, a lens 218, an imaging sensor 220, a controller or processor 222, a transmitter 224 and one or more power sources 215, such as for example batteries. According to one embodiment of the present invention, transmitter 224 may include one or more antennas 226 or antenna arrays that may be suitable for example for transmitting data such as for example image data to an external receiver or recorder. According to one embodiment of the present

invention, transmitter 224 may include control capability for, for example controlling the various operations of device 210, although control capability or one or more aspects of control may be included in a separate component. According to some embodiments of the present invention, transmitter 224 may be typically an ASIC (application specific integrated circuit), but may be of other constructions; for example, transmitter 224 may be a processor executing instructions. According to some embodiments of the present invention, device 210 may include a processing unit separate from transmitter 224 that may, for example, contain or process instructions. According to one embodiment of the present invention, processor 222 may control various components of device 210 and may be capable for example of varying a rate and/or intensity of illumination produced by illumination sources 216 or a frame rate or rate of image capture by imaging sensor 220. According to some embodiments of the present invention, the processor 222 (or one or more processors) may be disposed within the in-vivo device or external to the in-vivo device. Processor 222 or processing or computing capabilities may be part of a transmitter 224. In some embodiments, power may be supplied to device 210 through an external wireless power supply system. In some embodiments, device 210 may include a receiver that may receive a signal from a source external to a body, and such signal may activate or alter a functional state of device 210.

Device 210 may include, for example a handle or endoscope dock 228 by which an endoscope, laparoscope or other suitable device may releasably hold device 210 while device 210 is inserted or maneuvered into position in an in-vivo site.

Device 210 may include a focusing pivot, knob, button or lever 230, by which for example an external operator may adjust part of device 210. For example, an external operator may focus images onto imaging sensor 220 from outside of device 210 or outside of a body. Lever 230 (e.g., a focusing lever) may in some embodiments be connected to focusing shaft 232 which may for example be further connected to focusing screw 234. According to some embodiments of the present invention, a screw and/or a shaft need not be used. Another, possibly different shaped focusing element may be used. An end or base 236 of imaging sensor 220 or of for example a platform or base to which imaging sensor 220 may

be attached, may be moveably or slideably in contact with a thread 238 of focusing screw 234. According to one embodiment of the present invention, a side 240 such as for example a back of device 210 may include a fastener or immobilizing unit such as for example a vacuum pad 242 and pin 244 which may immobilize device
5 210 against an endo-luminal wall 246. Other suitable components or series of components may be used for adjusting a focusing system.

According to some embodiments of the present invention, device 210 and other devices discussed herein may be box-like in shape, spherical, cylindrical or may be shaped in other fashions as may be suitable for placement, positioning or
10 movement in-vivo and as may be suitable for angling or positioning imaging sensor 220 towards an area to be monitored. In some embodiments, device 210 may be an autonomous imaging device with for example a capsule-like shape.

According to some embodiments of the present invention, one or more in-vivo objects 248 may be located for example on or near the endo-luminal walls
15 246. The in-vivo object 248 may be for example a polyp or similar pathology, or another in-vivo object 248, such as a lumen section, surgical site, etc. According to one embodiment of the present invention, the receiver 200 may typically be or include a unit outside the body that receives signals, from a transmitter 224 within the imaging device 212. The generator 205 may include a unit located outside the
20 body, at a known location that may emit for example localized beams 202, waves or pulses onto an in-vivo object 248. The generator 205 may emit for example radiation, ultrasound, electro-magnetic energy or similar signals, waves or particles. The distance and direction needed to emit a beam or pulse from the generator onto the object 248 may in some embodiments be determined using a
25 calculated distance vector, such as vector 203 from imaging device 212 to object 248 and calculated distance vector 204, from imaging device 212 to generator 205. Adding the calculated vectors may determine the distance vector 206 from the generator 205 to object 248. The distance vector may typically be the direction and distance from one point to another, for example from object 248 to generator
30 205.

According to one embodiment of the present invention, the distance from an imaging device to an object may be calculated using for example illumination

that may be provided by for example illumination sources 216 and a reflection coefficient of such illumination against in vivo object 248. In some embodiments, the known intensity of the illumination emanating from illumination sources 216, reflected by viewed object 248, may correlate to their distance of such objects from the device 212. According to one embodiment, this intensity of reflected illumination may be measured by a data processor 222 in the device 212. (The intensity information may be transmitted to the receiver and thus processor 222 and/or its functionality of for example making an intensity determination may be calculated outside the device 212, for example, in an external workstation.) Thus, for example, an object that reflects light only dimly may be at a far end of the illumination range, whereas an object that reflects light brightly may be closer to the device 212. In an in-vivo area the distance from an illumination source 216 to in-vivo object 248 may generally be inversely proportional to the reflection coefficient of such object 248. In one embodiment, calculations of the distance from the illumination source 216 to the in-vivo object 248 may be based on the reflection coefficient or other known reflectance characteristics of the object 248 being analyzed. For example, the user may indicate an object or class of objects, such as for example polyps, for which the data processor 222 has stored characteristics such as, for example, a known average reflectance, or the user may enter a certain reflectance. Such reflectance coefficient may be combined or otherwise processed with the known illumination intensity and possibly other information such as for example transparency of GI fluids in the in vivo area being observed, may be used to calculate a distance or distance range between the illumination source and the in vivo object. Other suitable characteristics may be used.

Other embodiments of the invention may include an immobilizable in-vivo imaging device 212 having two imagers with adjustable angle capabilities. The distance between the two imagers may typically be known. The distance vector 203 from in-vivo imaging device 212 to in vivo object 248 may be determined, using for example parallax or triangulation. An embodiment may include two sets of one or more non-adjustable imagers with a known distance between imagers within the sets and between imagers from opposite sets. According to one

embodiment of the present invention, each of the plurality of imagers may be positioned at a known angle to allow for the implementation of the parallax or triangulation method when determining the vector distance from in-vivo imaging device to object.

5 According to one embodiment of the present invention, the distance from imaging device 212 to generator 205 may be calculated using the known or determined location of the imaging device 212. In some embodiments, the system may provide information about the location of the in-vivo device 212. Suitable tracking devices and methods are described in embodiments of the above-mentioned United States Patent Number 5,604,531 and/or United States Patent
10 Application Publication Number US-2002-0173718, filed on May 20, 2002, titled "Array System and Method for Locating an In-Vivo Signal Source", assigned to the common assignee of the present invention, and fully incorporated herein by reference. Other suitable location identification systems and methods may be used
15 in accordance with embodiments of the present invention. Upon determining the location of imaging device 212, the distance and direction from imaging device 212 to receiver 200 may be calculated based on the known location of receiver 200. According to one embodiment of the present invention, the location of generator 205 may typically be known, thereby allowing for the calculation of the distance
20 vector 207 from receiver 200 to generator 205. Calculating the vector addition or vector summation of the distance vectors 201 and 207 from imaging device 212 to receiver 200 and receiver 200 to generator 205 may yield the distance and direction from imaging device 212 to generator 205 e.g. distance vector 204.

 According to some embodiments of the present invention, with the
25 distance vectors from imaging device 212 to object 248 e.g. vector 203 and imaging device 212 to generator 205 e.g. vector 204 known, the distance vector 202 from generator 205 to object 248 may be determined. The determination may be made based on the sum of the calculated vectors.

 According to some embodiments an external receiver, such as receiver
30 200, may include a generator, such that calculating the distance between the imaging device and the receiver may be sufficient to enable localized radiation.

Reference is made to Fig. 3, a flow chart of a method in accordance with an embodiment of the invention. A distance vector 203 from imaging device 212 to object 248 may be determined using some of the above mentioned embodiments (block 300). The distance vector 201 from imaging device 212 to receiver 200 (block 302) and the distance vector 207 from receiver 900 to generator 905 (block 304) may be determined. The distance vector 204 from imaging device 212 to generator 205 may be calculated by implementing a vector addition of the distance vector 201 from imaging device 212 to receiver 200 and the distance vector 207 from receiver 200 to generator 205 (block 306). The distance vector 202 from generator 205 to object 248 may be determined by calculating the vector addition or vector summation of the distance vectors 203 and 204 from imaging device 212 to object 248 and from imaging device 212 to generator 205 (block 308). Other operations or series of operations may be used.

It will be appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described herein above. Rather the scope of the invention is defined by the claims that follow:

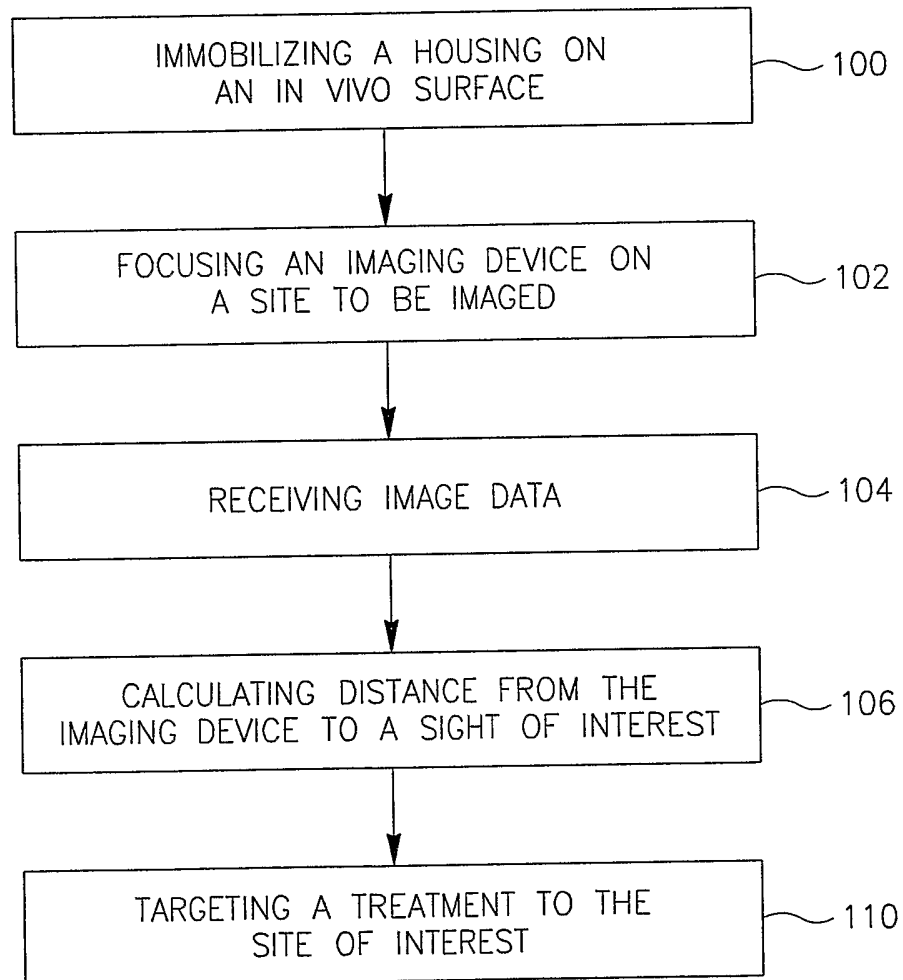
CLAIMS

We claim:

1. A system for treatment of an in vivo site comprising:
 - an in-vivo device comprising at least one image sensor and a transmitter;
 - 5 a receiver for receiving signals from said in-vivo device; and
 - a generator for irradiating said in-vivo site.
2. The system as in claim 1, wherein said in vivo site is a surgical site.
3. The system as in claim 1, wherein said in-vivo device is an autonomous in-vivo device.
- 10 4. The system as in claim 1, wherein said in-vivo device is an immobilizable in-vivo device.
5. The system as in claim 1, wherein said in-vivo device comprises an adjustable focusing mechanism.
6. The system as in claim 1, wherein said generator is selected from the group
15 consisting of: an ultrasound generator, an electro-magnetic energy generator and a radiation generator.
7. The system as in claim 1, comprising a processor to calculate a distance vector from said generator to said in-vivo site.
8. The system as in claim 1, comprising a processor disposed within said in-vivo
20 device.
9. The system as in claim 1, comprising a processor external to the in-vivo device.
10. A method for treating an in vivo pathology comprising:
 - locating a site within a body lumen;
 - 25 adhering an in-vivo sensing device to said site; and
 - directing to the site therapeutics by said in-vivo device.
11. The method as in claim 10, comprising immobilizing said in vivo device to said site.
12. The method as in claim 10, comprising focusing said in vivo device on said
30 site to be imaged.

13. The method as in claim 10, comprising calculating a distance vector from said site to a generator.
14. The method as in claim 10, comprising:
- determining a first distance vector from said in-vivo device to said site;
 - 5 determining a second distance vector from said in-vivo device to a generator; and
 - calculating a third distance vector from said generator to said site.
15. The method as in claim 10, wherein said first distance vector from said in-vivo imaging device to said in-vivo location is determined through parallax.
- 10 16. The method as in claim 10, comprising illuminating said site.
17. The method as in claim 16, comprising measuring an intensity of reflected illumination.
18. The method as in claim 14, wherein said first distance vector from said in-vivo device to said site is determined based on an intensity of reflected
- 15 illumination.

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*FIG.1*

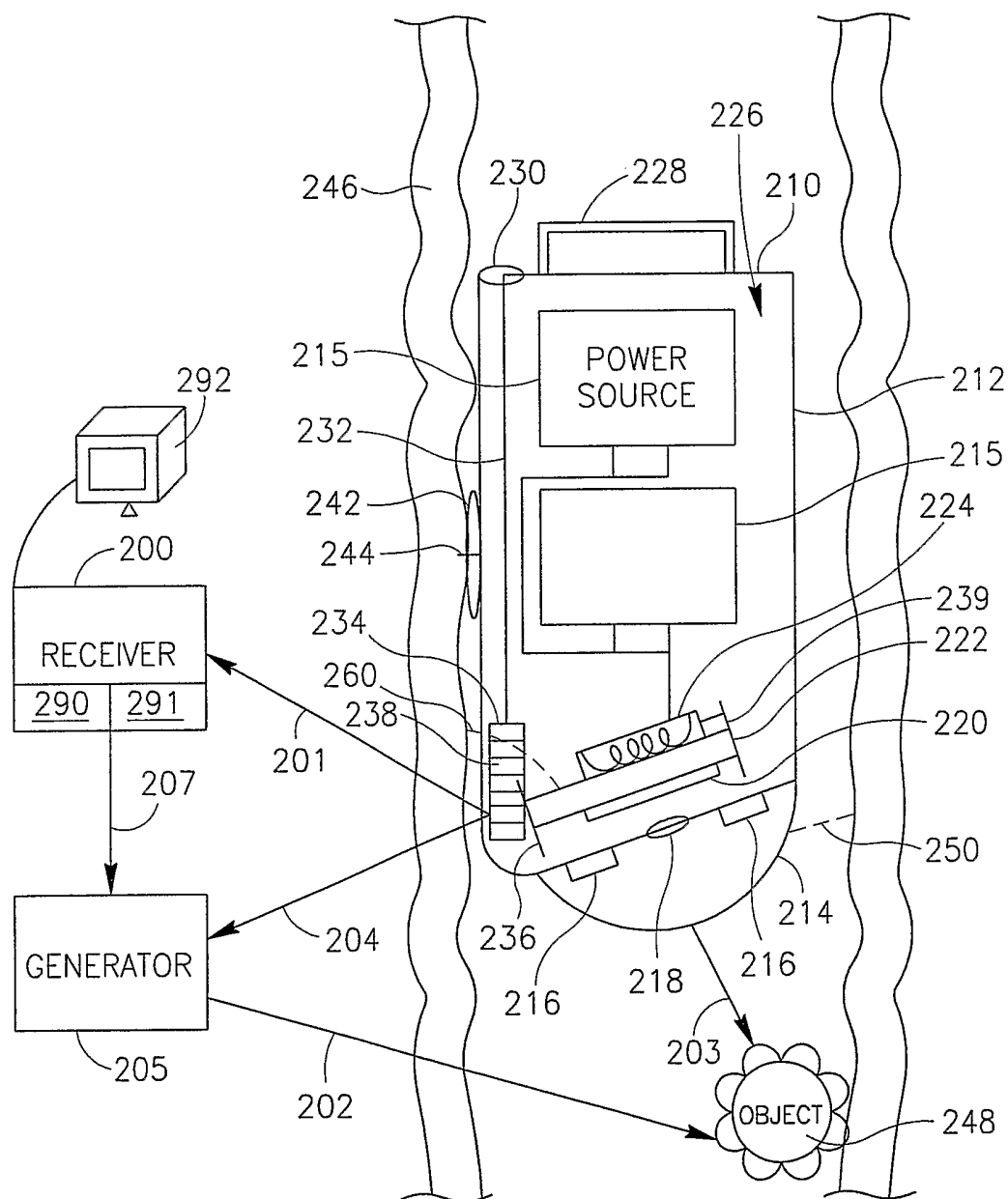


FIG. 2

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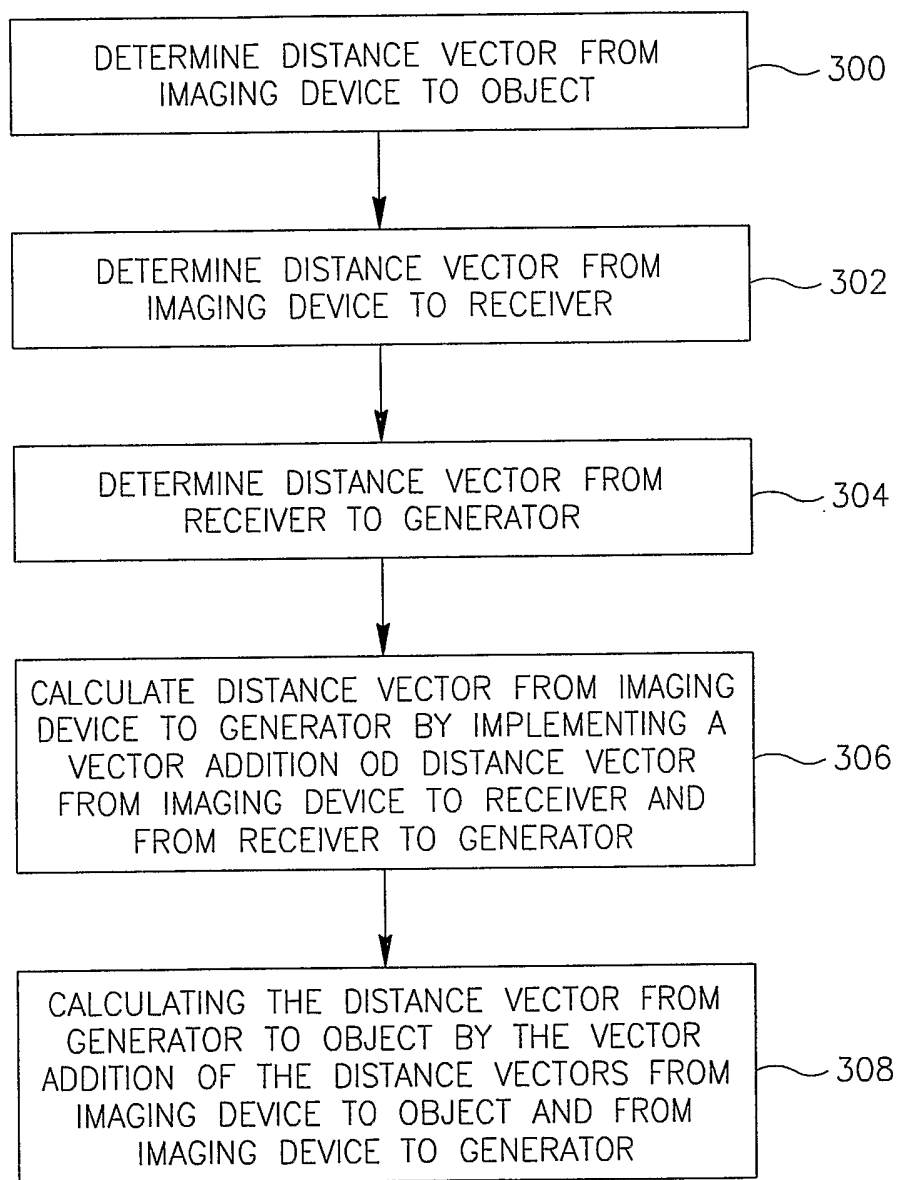


FIG. 3