Title: TRANSILLUMINATION OF BODY MEMBERS FOR PROTECTION DURING BODY INVASIVE PROCEDURES

Abstract

An apparatus and method for protecting a body member during a body intrusive procedure in a region adjacent the body member to be protected (14) includes infrared energy (18) introduced into a light guide (17) which is introduced into the body member to be protected; and visible light (2) is introduced into the region, either of the lights may be pulsed at the frame rate of a monitor (12) energized by a video camera (10) that receives light from such region, the camera being sensitive to infrared energy as well as visible light. In a further embodiment, infrared light is removed from the visible light and a polarizing filter may be employed to filter the light to the camera to reduce glare. A body member to be located or illuminated may be illuminated from one side and the location of the illuminator (112) detected by a probe (116) on the other side of the body member.
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TRANSILLUMINATION OF BODY MEMBERS
FOR PROTECTION DURING BODY INVASIVE PROCEDURES

RELATED APPLICATIONS

This application is a continuation-in-part of U.S. Application Serial No. 08/305,296 filed September 15, 1994 for "Transillumination of Body Members for Protection During Body Invasive Procedures" and is related to the Application Serial No. 08/190,516 filed February 2, 1994 for "Detection of Anatomic Passages Using Infrared Emitting Catheter" now United States Patent No. 5,423,321 issued June 13, 1995 and assignable to the same assignee as the present invention.

FIELD OF THE INVENTION

The present invention relates to methods and apparatus for transillumination of various parts of a living body to avoid damaging such parts during an invasive procedure and more specifically to the use of two different light sources in such procedures.

BACKGROUND OF THE INVENTION

Although the present invention is described in connection with protection of a ureter during a surgical procedure this is done merely for purposes of ease of illustration; the invention being useful for protection of various body parts lying adjacent a region subjected to an invasive procedure.

Currently practiced methods and devices used to transilluminate the ureters to permit ready location and
thus protection of the ureter during endoscopic procedures require the cystoscopic placement of a catheter housing and a fiber optic light guide into the lumen of the ureter. The distal portion of the fiber optic light guide is treated to allow light preferably to emit circumferentially from the wall of the fiber. The proximal end of the fiber is coupled to a visible light source. A second light source is coupled to an endoscope and introduced into the surgical site.

Light detection of the transilluminated ureter using typical illuminating catheters such as the Bush DL™ Ureteral Illuminating Catheter Set coupled to a light source during endoscopic procedures is facilitated with a camera. The camera projects the detected image of the transilluminated ureter on a monitor for visualization. Sufficient light from the predicate devices must traverse the ureter and overlying tissues with ample intensity to penetrate surrounding tissue and to overcome the illuminated field from the endoscopic light for the camera to detect light emanating from the transilluminated ureter. In the presence of the normally illuminated operative field from the endoscopic light, the camera frequently cannot detect light emanating from the transilluminated ureter. In an attempt to optimize and intraoperatively improve the performance of their device, Cook Urological, Inc. suggests that it may be necessary to dim or eliminate the endoscopic light
illuminating the surgical field. The same problems are encountered in open field surgery where the overhead lights in the operating room may have as great an effect as the endoscopic light source.

OBJECTS OF THE INVENTION

It is an object of the present invention to permit ready detection of preferably both an infrared light source as well as a more standard light source as opposed to only an endoscopic light source during an invasive procedure in a region of a body adjacent the ureter or other body member to be protected.

It is another object of the present invention to provide a system and method permitting ease of discrimination of light energy emanating from a body member to be protected during an invasive procedure adjacent said body member from light introduced to illuminate the region of the procedure adjacent such body member.

It is yet another object of the present invention to protect a body member during a surgical procedure adjacent thereto by emitting modulated electromagnetic radiation from such member to permit ready detection of such radiation in the presence of visible light illuminating the area of the procedure.

Still another object of the present invention is to emit infrared light from a body part to be protected during a surgical procedure and to maintain the
surgical site otherwise free of infrared energy by filtering out infrared energy from an endoscopic or like light source if such is employed.

Yet another object of the present invention is to emit continuously, electromagnetic energy from a body member to be protected during an invasive procedure in a region adjacent thereto and to pulse a light employed to illuminate the region during the procedure.

Another object of the present invention is to synchronize emissions of electromagnetic energy from a body to be protected during a surgical procedure in a region adjacent thereto with emission of light into the region for illumination thereof.

Still another object of the present invention is to synchronize a camera shutter with periodic emission of light into a region being subjected to an invasive procedure with periodic emission of detectable energy from a body member to be protected from injury during such invasive procedure.

Yet another object of the present invention is to couple an optical fiber employed to detect light emitted by a source located in a body part to be protected, to a surgical instrument to be inserted into a body cavity in which a procedure is to be conducted.

It is still another object of the present invention to emit infrared energy from a body member to be protected during surgery into a region illuminated by
an endoscopic light source from which infrared energy has
essentially been removed.

Another object of the present invention is to
employ an infrared energy source to illuminate a region
of a body and view the region with a camera sensitive to
both visible and infrared light energy.

Yet another object of the present invention is
to transilluminate a body member or region with infrared
energy to enhance the view of the region whereby to
facilitate a surgical procedure.

Still another object of the present invention
is to transmit infrared light energy down a nerve to be
protected during a surgical procedure to cause the nerve
to become an infrared light energy emitter.

**BRIEF DESCRIPTION OF THE PRESENT INVENTION**

The use of infrared emission detection is
central to the technology of the present invention. In
particular, the technology takes advantage of the
inherent transmissivity of infrared through biological
tissues in the range from 700 nm to 1,300 nm. Optically,
all biological tissues are considered composite
structures consisting of a scattering medium imbibed with
various molecular components that absorb light at
specific wavelengths. The amount of light absorbed by
different molecules is dependent on the chemical and
physical properties of the molecule. In the visible part
of the spectrum (400 to 650 nm), intense absorption due
to hemoglobin and light loss caused by scattering prevents transmission of visible light over more than a few millimeters of tissue. In the infrared spectrum above 1,300 nm, water present in tissue acts as an effective absorber of infrared at this wavelength, again limiting the transmission of infrared longer than 1,300 nm to a short distance. In the infrared range of 700 to 1,300 nm, however, a significant amount of infrared light can be transmitted through several centimeters of biological tissue. This window of high transmissivity is due to the lack of molecular components that absorb infrared between 700 nm and 1,300 nm.

The present invention makes use of the fact that infrared energy can be transmitted through several centimeters of biological tissues to implement various procedures such as protection of organs, etc., during invasive procedures adjacent an organ, to transilluminate an organ to locate it and view it and to render nerves visible over a length thereof.

In a first embodiment of the invention a probe is employed to detect infrared energy during a laparoscopic operation. An endoscopic light source is pulsed while continuous emissions of infrared energy are provided from a body member to be protected, such as a ureter, duct, colon, blood vessel or other body member. The visible and infrared light energies are directed by the probe to a video camera to a monitor. The endoscopic
light source is pulsed on at every other frame or half frame of an interlaced display on a monitor so that every other full frame or half frame displays both the member to be protected and the area of the operation and the next frame or half of the interlaced frame displays only the emission from the body member to be protected. Thus the body member emission is enhanced.

In a second embodiment of the invention an infrared light source disposed in a body member to be protected during surgery or other invasive procedure in the region of said body member, is pulsed on when visible light from the endoscopic light source is projected into such region is off and vice versa. The on-time of the source in the body member is synchronized with operation of the shutter of a video camera employed to project an image of a body member on a monitor. In this arrangement, the body member and the region of the invasion of the body are displayed in alternate frames on the monitor. As will become apparent below, elimination of infrared energy from the endoscopic light source further enhances visualization of the member to be protected.

In the event the procedure involved is an open body procedure and the visible light source is the standard overhead array of lights in an operating room, the visible lights cannot be pulsed so that only the infrared source is pulsed. The detectors then must be
sensitive only to infrared and/or to a 12 KHz signal imposed on the infrared light.

In another embodiment of the invention, the light fiber employed to detect light from a body member in the surgical area is secured to a surgical instrument to be inserted into and used in such area. The fiber may be carried by a sleeve slipped over the instrument which may be a scissor, a stapler, or the like. The fiber may be mounted so as to be a forward looking or single or multiple fibers may be mounted so as to be side looking or both as determined by the requirements of the surgical site and instrument.

In still another embodiment of the invention, an audible alarm can be used in the former two embodiments of the invention and is synchronized with the infrared light source. Thus such alarm does not respond to infrared energy of the endoscopic light source and the level of infrared energy to produce detection may as a result be reduced to provide information at an even greater distance from the member to be protected than might otherwise be the case. The alarm may be of constant amplitude or may vary as a function of the distance of the probe from the infrared emitter.

In a further preferred embodiment of the invention, infrared light energy is emitted from a body part to be protected during laparoscopic procedures while the rest of the surgical site is infrared free, this
being accomplished by removing infrared energy from the light emitted by the endoscopic light source employed to illuminate the surgical site. This effect is achieved by employing an infrared blocking filter between the endoscopic light source and the surgical site. In this embodiment, and useful in the other embodiments, the endoscope has an annulus of optic fibers for conducting light from an endoscopic light source to the surgical site and a centrally located lens for transmitting light from the surgical site to a CCD of a video camera, the lens having a focal length to accommodate the length of the endoscope.

In such embodiment of the invention the infrared blocking filter may be inserted into the light path from the endoscopic light source whereby infrared light energy from an emitter in or adjacent to an organ or the like to be protected will be the only substantial source of infrared energy in the operative region. Thus response of the alarm will be limited to infrared energy from the body to be protected. Further the video camera is made sensitive to both visual and infrared energy the infrared energy source will be clearly identified.

The present invention also discloses the use of transillumination of a region subject to a surgical procedure. In one such illustrative application an infrared energy source is inserted into the region of the knee joint and an infrared energy probe connected to a
video camera and monitor is either inserted into the opposite side of the joint or placed on the surface of the skin on the opposite side of the joint. Because the articular cartilage and surrounding tissues are generally white and translucent with not great color contrast, the transillumination yields improved overall illumination of the surgical site while improving definition of the structures lying between the source and the probe.

In a laparoscopic procedure, the location of an infrared energy source used to transilluminate internal organs, tissues, bones, etc., may be detected by an infrared detector probe and positioning is rendered less difficult. An endoscopic source and detector probe may then be accurately positioned in the operative region for detection of the region to be treated.

In the protection of nerves, it has been found that when an infrared energy emitter is placed in contact with a nerve, the infrared energy is transmitted along the nerve which then becomes an infrared energy emitter along a length thereof, thus identifying the location of such length. The length of the nerve that is thus identified depends upon the energy of the infrared energy source.

The infrared energy source in the original system of the present invention was a 5 milliwatt source. The system has been configured to utilize a 1 watt source and in fact uses two such sources. In tests conducted to
date only 250 mW have been used. The second source is used to transilluminate an organ such as the bladder while an infrared emitter is inserted for instance in the ureter. The transillumination may assist in locating various members at the actual surgical site. Thus blood vessels, ligaments, ducts, stones in various organs, all or any one of which may be involved in the surgical procedure can be located while at the same time the ureter, etc. are protected utilizing the other laser source.

In all of the above embodiments a polarizing filter may be placed in the light path to the camera to reduce glare.

All of the above systems may be operated with NTSC, PAL or SECAM video systems so that as appropriate frames may be interlaced as indicated hereinafter if so desired.

The above and other features, objects and advantages of the present invention, together with the best means contemplated by the inventor thereof for carrying out the invention will become more apparent from reading the following description of a preferred embodiment and perusing the associated drawings in which:

**BRIEF DESCRIPTION OF THE DRAWINGS**

Figure 1 illustrates a first embodiment of the present invention;
Figure 2 illustrates a second and a third embodiment of the present invention;

Figure 3 illustrates a surgical scissor with a fiber bearing sleeve disposed about the instrument;

Figure 4 illustrates the endoscope and related equipment provided in accordance with the present invention;

Figure 5 illustrates a side and end view of the endoscope employed with adapters that can accommodate various filters;

Figure 6 illustrates a block diagram of the control circuits of a preferred embodiment of the invention;

Figure 7 illustrates the preferred embodiment utilizing the light from both diode lasers of Figure 6;

Figure 8 illustrates the use of the IR emitter and probe to locate a body to be subject to a procedure;

Figure 9 illustrates the use of the present invention to illuminate and view a knee joint during arthroscopic surgery; and

Figure 10 illustrates the use of IR energy to define the location of a nerve or nerve bundle.

**DETAILED DESCRIPTION OF THE PRESENT INVENTION**

Referring specifically to Figure 1 of the accompanying drawings, there is illustrated a diagram of a system employing a pulsed laparoscopic visible light source 2. The source 2 is turned on and off by a source
of energizing pulses 4 at a rate that is synchronized with the frame rate of a monitor 12 via lead 7.

The endoscope 6 consists of a lens system surrounded by a fiber optic bundle 6a. The light cable 3 couples the endoscopic light source 6 to the fiber optic bundle 6a of the endoscope. During endoscopic procedures, the surgical field is illuminated using the endoscope 6 coupled to the endoscopic light source 2 via the light cable 3. Specifically, the distal end of the endoscope 6 located internally of a body in a region to be illuminated. The proximal end of the endoscope 6 has an adapter 52 (Figure 4) that couples the distal end of the light cable 3 to the proximal end of the internal fiber optic bundle 6a of the endoscope 6. The proximal end of the light cable 3 is coupled to the light source 2. Light exits the most distal end of the fiber optic bundle 6a at the distal end of the endoscope 6. The lens system of the endoscope 6 transmits the illuminated surgical field to the monitor via the camera 10.

Standard endoscopic optics directs light supplied by the light source 2 and reflected by the body tissue in such regions to the camera where the signals are processed and displayed on the monitor. Normally such cameras have a filter over the sensing chip to block out infrared. In this instance such filter is not used so that the camera can respond to energy of such wavelengths emitted from the fiber optic light guide 6a
as well as visible light. In such a case an IR filter normally found in video cameras is removed from the CCD of the camera and is replaced by a sapphire window placed over the CCD to render it responsive to both IR and visible light. In order to insure that the only source of IR in the surgical field is emitted by the light guide 17, an infrared energy filter is inserted into the light path from the source 2.

In the illustrated example of a laparoscopic procedure in Figure 1, the body member to be protected is a ureter designated by reference numeral 14. A catheter 16 is inserted into the ureter and a fiber optic light guide 17 is inserted into the catheter and may be conditioned to emit infrared energy in all directions as fully disclosed in said parent of this continuation-in-part application, the full disclosure of which is incorporated by reference. The infrared energy is supplied by a 50 mW to 250 mW infrared or visible range light source 18 coupled to the fiber optic light guide 17.

In operation of the system, the continuous infrared energy is transmitted to the fiber optic light guide 17 and via light guide 6 (see discussion of Figure 2) to the video camera which provides an image on the screen of the monitor 12. The intermittent visible light is also displayed on the monitor thereby displaying a view of the region being investigated but the display of
the infrared image is stronger and readily locates the ureter in this case in the field of view appearing on the monitor. During the period the light source 2 is turned off, the display of the ureter light source clearly predominates. When IR is removed from the light supplied by source 2, pulsing of this source is no longer necessary and the IR source may be pulsed to render it more readily detected. This latter embodiment is preferred.

Referring to Figure 2 there is illustrated a second embodiment of the present invention employing synchronization of various elements of the system. Again light source 18 supplies infrared energy to the fiber optic light guide 17 but the source 18 is pulsed via a lead 20 from a sync source 22. The sync source 22 provides pulses to a camera microprocessor 24 that controls the shutter of the camera 10 and the sweep of the monitor 12. The sync generator also controls the energization of the light source 2. Further there is provided an infrared light sensor 26 that produces an audible sound (and/or visual display) whenever infrared is transmitted thereto via a light guide 28 also introduced into the region of interest via a trocar 30.

Note in Figure 2, a dashed line 32. This line comes from the sync generator 22 and pulses the light sensor 26 in synchronism with the light source 18. With such procedure, the sensor 26 cannot be triggered by
light from the endoscope source 2 and a low threshold may be used so that infrared emission from the ureter may be detected at a greater distance than would be possible otherwise.

In operation, the sync generator 22 alternates energization of the light sources 2 and 18 so that the catheter light is on when the endoscope light source 2 is off and vice versa. Such operation provides great flexibility of the display on the monitor. If the camera is turned on only when the source 18 is energized then only the ureter is displayed. If the camera 10 is turned on only when the endoscopic light source 2 is energized then only the surgical area is displayed (not a good practice if a body member is endangered by the procedure). Alternatively and preferably in this embodiment, the system is established such that the camera 10 is turned on with each light source so that with proper synchronization and preferably the use of an NTSC system the two areas are displayed in alternate interlaced frames on the monitor.

The sync generator 22 may reverse the on/off cycles relative to the opening and closing of the camera shutter. Specifically maximum view of the ureter is achievable with a reversal of the cycles of the IR source and the endoscope source relative to the camera shutter opening and closing.
TABLE 1

<table>
<thead>
<tr>
<th>Camera Shutter</th>
<th>OPEN</th>
<th>CLOSED</th>
<th>OPEN</th>
<th>CLOSED</th>
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<tr>
<td>IR Source</td>
<td>ON</td>
<td>OFF</td>
<td>OFF</td>
<td>ON</td>
</tr>
<tr>
<td>Endoscopic Source</td>
<td>OFF</td>
<td>ON</td>
<td>ON</td>
<td>OFF</td>
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With this arrangement a high degree of differentiation is obtained and reference is made to Table 2 on Page 20.

Continuing with a description of the system elements, the probe 28 and associated circuitry from the light sensor provide an audible signal (light may be employed) the intensity of which may or may not vary with proximity of the probe 28 to the ureter (see the discussion of Figure 6). If the signal does vary the location of the ureter may be determined with greater precision than may be possible with the probe 6 - monitor system. The probe 28 shows on the monitor and the relative position of the surgical instrument relative to the ureter is more readily determinable by the position of the surgical instrument relative to the probe 28.

Referring to Figure 3 of the accompanying drawings, there is illustrated a surgical scissor generally designated by the reference numeral 34. The two blades of the scissor, only one blade 36 being illustrated, are carried at the end of a hollow shaft 38 having the operating mechanism for the scissor disposed
therein. The scissor is actuated by squeezing together two hand grip members 40 and 42.

A sleeve 44 is slipped over the shaft 38 and carries an optical fiber 46 in a passage formed in the sleeve. An end 48 of the fiber is connected to a light sensor such as camera 10 or light sensor 26 of Figure 2 or other suitable sensor such as illustrated in the aforesaid application, Serial No. 08/190,516 filed February 2, 1994.

The element designated 50 in Figure 3 is the infrared emitting fiber 17 in the organ to be protected, for instance, a ureter. The fiber 46 illustrated in Figure 3 is a forward looking fiber but could also be a side looking fiber.

Following on Page 20 is a Truth Table, Table 2, of operation with the system of Figure 2, with the camera shutter open and a 5 mW source. When both lights are on continuously the response relative to both of the light sources by the monitor and the audible source is acceptable but enhancement is preferred. The monitor display does not provide the sharp differentiation that would be preferred.

When only the catheter source is "on" the display of the ureter, in this instance, is clear and sharp since infrared from the endoscopic source does not interfere with the signal generator 26.
If the threshold on the audible detector is low enough an audible signal may be detected even though the infrared source is off. This problem may be addressed by pulsing the audible signal source "on" via lead 32 only when the infrared source is energized or by eliminating the IR energy from the endoscopic source. Under either of these circumstances there is no problem with the visual light and the threshold can be set relatively low on this detector.

When the camera shutter is closed the Truth Table 3 on Page 21 applies. Specifically only the audible signal generator 26 is operative and the response is the same as in the Table above.
Truth Table outlining the performance of the synchronized dual light sources used to transilluminate the ureters during endoscopic surgery. The camera shutter is open.

<table>
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<tr>
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<th>Catheter Light Source</th>
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<td>10</td>
<td>Endoscope Light Source</td>
<td>ON</td>
<td>OFF or IR Blend</td>
<td>ON</td>
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<td></td>
<td>Visual Detection on Monitor</td>
<td>Marginal Not Efficient</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>Audible Detection Using Light Probe</td>
<td>Marginal Not Efficient</td>
<td>YES</td>
<td>NO but possible</td>
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<td></td>
<td>Audible Detection Using Pulsed Light Probe</td>
<td>Marginal Not Efficient</td>
<td>YES</td>
<td>NO</td>
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<td>20</td>
<td>Endoscope with IR Filter</td>
<td>ON</td>
<td>OFF</td>
<td>ON</td>
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<td>25</td>
<td>Visual Detection on Monitor</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
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<td>30</td>
<td>Audible Detection Using Light Probe</td>
<td>YES</td>
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<td>NO</td>
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<tr>
<td>35</td>
<td>Audible Detection Using Pulsed Light Probe</td>
<td>YES</td>
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TABLE 3

Truth Table outlining the performance of the synchronized dual light sources used to transilluminate the ureters during endoscopic surgery. The camera shutter is closed.

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<td>Visual Detection on Monitor</td>
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<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>Audible Detection Using Light Probe</td>
<td>Marginal Not Efficient</td>
<td>YES</td>
<td>NO but possible</td>
</tr>
<tr>
<td>Audible Detection Using Pulsed Light Probe</td>
<td>Marginal Not Efficient</td>
<td>YES</td>
<td>NO</td>
</tr>
</tbody>
</table>

The same changes as reflected in Table 2 occur if the IR is removed from the endoscopic light source.

The pulsing of the infrared or a visible light source 18 coupled to the fiber optic light guide 17 greatly enhances the ability of the surgeon or other health care operative to distinguish between light emanating from the infrared source and visual light reflected from the tissue illuminated by light from an endoscopic or ambient light source.
In furtherance of this concept, the audible signal may be modulated with an identifiable signal to insure that the sound does not simply fade into the background of consciousness. For instance, a 1500 cycle per second tone can be imposed on the output during each "on" cycle. This approach reduces the effect of noise from the light sources. The 1500 Hz signal may be applied to a 50% duty cycle 12 KHz square wave.

The audible signal generator could also be a visual light source that would blink at a rate that varies with proximity of the probe to the body member to be protected or just blink when the ureter is approached.

Typical specifications for this system are:
1. A 5 mW infrared LED or two variable 250 mW infrared laser diodes.
2. An infrared emitting segment of 20 to 25 cm.
3. An ST type optical connector on the proximate end of the light detector probe. Both the light probe and guide are manufactured by Ethox Corporation according to the specification.
4. Government regulations for a Class I laser required that the power emitted from the fiber optic light guide should not exceed 60.8 μW from the hottest point on the fiber at a distance of 20 cm through a 7 mm operation.
5. Ureteral catheter - 65 cm long with an O.D. of 2.3 mm and three holes for drainage from TFX Medical.

6. The light guide is an Eska Fiber from Mitsubishi.

7. Light source spectrum of 620 nm to 1,000 nm.

8. The camera is a Model 2070D manufactured by Envision Medical Corporation of Santa Barbara, California.

A further embodiment of the present invention is illustrated in Figures 4 and 5 of the accompanying drawings. The system illustrated in Figure 4 is similar to that illustrated in Figure 1 and where appropriate the reference numerals of Figure 1 are employed.

It is the desire of this embodiment to create an essentially infrared free zone, except for emissions from the ureter, in an effort to unerringly distinguish the light from the ureter from any other source. In order to accomplish this result, an adapter 52 is employed. The light source 2 is a halogen or Xenon light source both of which are typically rich in infrared energy. To eliminate the infrared energy from the source, a Cyon (#2) filter (not illustrated) is inserted into the adapter 52 or into the light cable 3 of Figure 1 to block the infrared energy. The filter is available from Hoyo, No. 8405.
The filtered light is applied to endoscope 6 which transmits the filtered IR free light to the surgical site 54 via fiber optic bundle 6a of Figures 1 and 5. A lens system (diagrammatically 56) is disposed inside of the endoscope 6 and focuses light on the CCD of a camera 10 through a camera coupler 58. The camera coupler may have a polarizing filter to minimize glare from the illuminated surgical field. The adapter 52 may be constructed to receive removably an IR filter so that if the system of the present invention is not to be used the filter may be removed.

The system illustrated in Figures 4 and 5 is readily adapted to the structure of Figures 1 and 2, the endoscope 6 of Figure 5 focusing the light at the end of the endoscope and directing it via the coupler 58.

In a system employing a 250 mW IR source, marginal or acceptable but not too good results are to a great extent eliminated and more importantly the distance over which the IR energy can be detected is greatly increased. The system to be described may employ 1 watt laser diodes but in the system tested lasers were set at 250 mW. Such a circuit is illustrated in Figure 6 of the accompanying drawings.

Referring specifically to Figure 6, a power supply 60 is controlled by an on/off switch 62. The supply 60 provides power to two voltage regulators 64 and
66 associated with an audio section 68 and an IR source section 70, respectively.

The audio section 68 includes a port 72 for a light detector probe, such as probe 28 of Figure 2. The port feeds a voltage controlled oscillator 74 via a tone decoder 76 and an inverter and integrator 78. The tone decoder passes a signal at the frequency of modulation provided by a pulse generator 80 in the IR section 70, 12 KHz.

The voltage control oscillator provides a fixed frequency whenever the signal from the inverter and integrator element 78 exceeds a certain threshold. A variable frequency may also be employed if desired. The signal developed by the integrator 78 is supplied to the VCO and thence to an amplifier 82 feeding a speaker 84 or perhaps a light. The frequency output of the VCO can vary between 440 Hz and 4400 Hz but as indicated above is currently set to a single tone. A volume control 83 controls the output signal from the amplifier 82.

Referring now to the IR source section 70, the voltage regulator 66 is coupled to pulse generator 80. The pulse generator can be switched between continuous wave or pulsed operation. In the pulsed mode operation may be at 4 Hz with a 12 KHz tone. In the continuous mode a 12 KHz signal with or without 1500 Hz tone is emitted. The pulse generator imposes the tone on the signal produced by the generator. The pulse generator
supplies its output signal to a laser driver circuit 85. The drive circuit drives two laser diodes 86 and 88. Although 1 watt lasers may be employed, the laser diodes currently employed are set to operate at a maximum power of 250 mW. Potentiometers 96 and 98 on the laser drive circuit 85 are employed to initially set the maximum output of the laser diodes. Once the maximum output is set the wattage output may be varied from 50 mW to 250 mW; control being affected by a laser power control operated by a knob 90. The IR outputs from the laser diodes 86 and 88 are supplied to probes, such as the probe 28 of Figure 2 via ports 92 and 94, respectively.

Simulated tests have been conducted to determine the relative effectiveness of the prior art ureteral detectors, inventor's prior system and the system of Figure 6. A piece of bovine muscle was used of a thickness that permitted detection by the prior art Bush devices from Rusch, Inc. and Cook Urological. Tests were conducted using a Stryker 782 Solid State Color Medical Video Camera coupled to a Quantum 3000 light source to transilluminate the specimen. Display was on a Sony 13" monitor and/or an audible signal was used for detection.

The performance of the various devices was as follows:
TABLE 4

Comparison of the system of Figure 6, Bush Ureteral Illuminator (Rusch, Inc.) and the Bush DL\textsuperscript{2} Ureteral Illuminating Catheter (Cook Urological) under simulated open surgical procedures.

<table>
<thead>
<tr>
<th>System</th>
<th>Dim Overhead Lighting</th>
<th>Full Overhead Lighting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detector Probe Coupled to the IR Illuminator</td>
<td>30 mm</td>
<td>30 mm</td>
</tr>
<tr>
<td>Bush Ureteral Illuminator (Rusch, Inc.)</td>
<td>8 mm (very faint)</td>
<td>4 mm</td>
</tr>
<tr>
<td>Bush DL\textsuperscript{2} Ureteral Illuminating Catheter (Cook)</td>
<td>8 mm (very faint)</td>
<td>4 mm</td>
</tr>
</tbody>
</table>
Comparison of the system of Figures 2 and 6, Bush Ureteral Illuminator (Rusch, Inc.), and the Bush DL™ Ureteral Illuminating Catheter (Cook Urological) under simulated laparoscopic procedures.

<table>
<thead>
<tr>
<th>System</th>
<th>Dim Laparoscopic Lighting</th>
<th>Full Laparoscopic Lighting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detector Probe Coupled to the IR Illuminator</td>
<td>30 mm</td>
<td>30 mm</td>
</tr>
<tr>
<td>Imaging System</td>
<td>12 mm</td>
<td>8 mm</td>
</tr>
<tr>
<td>Bush Ureteral Illuminator (Rusch, Inc.)</td>
<td>8 mm (very faint)</td>
<td>4 mm</td>
</tr>
<tr>
<td>Bush DL™ Ureteral Illuminating Catheter (Cook)</td>
<td>8 mm (very faint)</td>
<td>4 mm</td>
</tr>
</tbody>
</table>

Transillumination and electronic detection of the test tissue using the system of Figure 6 is approximately three fold more efficient when compared to the Bush Ureteral Illuminator (Rusch, Inc.) and the Bush DL™ Ureteral Illuminating Catheter (Cook Urological) under simulated open and laparoscopic procedures. It should also be noted that detection by the apparatus of Figure 6 did not vary over the 30 mm range. The apparatus of Figure 2 was twice as sensitive of the prior art devices.

In the preferred embodiment of the invention the light from the endoscope has the IR removed and the camera is sensitive to both IR light and visible light energy. When performing a laparoscopic procedure,
pulsing is not essential but is preferred and also a polarizing filter may be used to reduce glare.

In an open body procedure, infrared light energy can, but not readily, be removed from the overhead lights and pulsing of at least the infrared light energy is strongly preferred. The polarizing filter may also be used.

The signals from the CCD may be processed in a variety of ways to enhance the visibility of the infrared image. Such enhancement may include contrast enhancement, additional gain, digital edge detection, addition of pseudo-color, use of the full 1 watt of the laser diode and the like.

Referring now specifically to Figure 7 of the accompanying drawings, there is illustrated the use of the second diode laser of Figure 6. In the situation illustrated, surgery is to be performed on a bladder designated by reference numeral 100. Ureter 102 is illuminated by light fiber 104 from a light source 106. The bladder 100 is transilluminated by a second light probe 108 energized by a second laser from a source 110. In practice the two sources are those illustrated in Figure 6 and would usually be enclosed within a single case.

Except for the second source, the system will be that illustrated in Figures 2 and 6 combined. The second IR source permits the surgeon to clearly see the
site of the operation and the interior of the organ to be treated. In such a situation the full 1 watt of energy of the laser supplying probe 100 may be employed.

Referring specifically to Figure 8 there is illustrated another example of use of the present invention to transilluminate tissue to be inspected or operated upon.

An IR emitting light probe 112 is inserted into the body and the probe 112 is to be positioned in a specific location behind tissue 114. An IR detector probe 116 is also inserted into the body on the opposite side of the tissue 114 from the probe 112. The emitting probe 112 is maneuvered into the desired position with the help of detector probe 116. The site of the operation is viewed on monitor 118 by use of endoscope 120 and associated members including visible light source 122. The use of the IR emitting probe 112 and detector probe permits the position of probe 112 to be determined at all times particularly during a scanning procedure.

A particularly useful approach to arthrosopic surgery employing the apparatus of the present invention is illustrated in Figure 9 of the accompanying drawings. A knee joint 124 to be repaired is viewed by an endoscope 126 inserted into leg 128 in alignment with the joint 124 to be repaired. The joint is flooded with infrared light by a light probe 130 positioned preferably against the
skin of the leg 128 opposite the joint 124 and thus on
the opposite side of the joint from the endoscope 126.

The emitting probe 130 is finished with a flat
end placed against the skin outside the body. Because
the articular cartilage and surrounding tissues are
generally "white and translucent" with less color
contrast when compared to laparoscopy, the back
transillumination yields improve overall illumination of
the viewed surgical site while providing back
transillumination of structures between the emitting
probe and the endoscope. Applying the infrared light
through the skin, diffuses the light and produces good
overall illumination of the area.

Referring to Figure 10 there is illustrated a
procedure for protecting nerves from damage during
invasive procedures. It has been found that if an IR
light emitting probe is brought into contact with a
nerve, IR energy is transmitted along the nerve and it
becomes an IR emitter.

In the peripheral nervous system, nerve fibers
are grouped in bundles to form the nerves. Nerves have a
translucent and whitish appearance because of their
myelin content. It is imperative that they are not
inadvertently damaged during surgery. As an example and
reference is made to Figure 10, the inferior alveolar
nerve 130 enters the lower jaw or mandible 132
posteriorly through the mandibular foramen 134. It gives
sensory nerve supply or innervation to the gums and teeth of the mandible. The inferior alveolar nerve 130 exits the mental foramen of the mandible anteriorly as the mental nerve 136 giving sensory innervation to the skin over the chin and the lower lip.

Over one million dental implants are placed in the mandible per year. Frequently, during dental implant placement procedure, it is important to locate the interior alveolar nerve as it courses in the mandible. Obviously, if an implant is placed in the mandible that transects or compresses the inferior alveolar nerve, then ensuing and irreversible sensory loss (feeling) to the lower lip and chin may follow. Thus, locating the inferior alveolar nerve prior to implant placement has significant clinical advantages.

The apparatus of Figure 10 illuminates the inferior alveolar nerve 130 using an infrared emitting probe 138 with a spherical end. The infrared emitting probe is placed against the mental nerve 136 as it exists the mental foramen 140. The inferior alveolar nerve 130 is transilluminated posteriorly. During the operative procedure, either the imaging system or the detector probe coupled to the detector panel of the IR illuminator peers into a prepared bony site 142 that receives the implant. If the inferior alveolar nerve is detected, then the surgeon can take precautions against injury, i.e., stop drilling or use a shorter dental implant.
Thus the illumination of a length of the nerve permits it to be viewed and preserved. The procedure is applicable to protection of important nerve structure wherever located.

The device disclosed herein will often be sold as an article of commercial in kit form in which the various of the elements may be sold as a package. Such could include the light source, the fiber for insertion into an organ, vessel or the like, a catheter which may or may not be used with the aforesaid light fiber, a camera, camera microprocessor, sync generator light source, light sensor, pulse generator and/or audible or visual proximity sensor with ancillary equipment as required. The article may be that illustrated in Figure 1, or Figure 2, the sleeve of Figure 3 or additional equipment of Figures 4 to 10.

Once given the above disclosure, many other features, modifications and improvements will become apparent to the skilled artisan. Such features, modifications and improvements are, therefore, considered to be a part of this invention, the scope of which is to be determined by the following claims.
WHAT IS CLAIMED IS:

1. An apparatus for reducing the danger of damage to a body member located in a region of an intrusive procedure in a body in which the body member is located comprising,

   a fiber optic light guide insertable into the body member to be protected,

   a source of light energy having at least strong infrared light energy,

   means for introducing such energy into said light guide,

   said light guide having a region for emitting said infrared energy from said body member,

   a source of visible light energy,

   means for introducing said visible light energy into said region,

   means for pulsing at least one of said sources of light energy, and

   means for locating the body member by detecting the location of the source of infrared light energy in the body.

2. The apparatus according to claim 1 further comprising

   means for energizing said sources in alternation.
3. The apparatus according to claim 1 further comprising
   a signal device for stimulating a human sensory response,
   said signal device having a probe insertable into a body adjacent an operation site for transmitting light energy to said signal device, and means for rendering said signal device operative only when said infrared energy source is energized.

4. The apparatus according to claim 1, 3 or claim 20 further comprising
   a camera responsive to at least infrared energy,
   a second light guide for directing energy from said sources to said camera.

5. The apparatus according to claim 4 wherein said camera is responsive to both visible and infrared light energy.

6. The apparatus according to claim 4 wherein said camera is a video camera, and further comprising a video monitor for receiving signals from said video camera and displaying said signals on its screen.
7. The apparatus according to claim 6 further comprising
means for pulsing said sources on and off in alternation, and
means for synchronizing the pulsing of said sources with the scan of said monitor.

8. The apparatus according to claim 7 further comprising
means for synchronizing the shutter of said camera with said pulsing of said sources.

9. The apparatus according to claim 7 wherein said monitor operates on the NTSC system and images produced when each said source is energized are displayed alternately by the interlaced scans of said monitor.

10. The apparatus according to claims 1 or 20 further comprising
a camera responsive to both infrared energy and visible light energy,
means for directing infrared energy to said camera,
said last-mentioned means directing visible light reflected from said region to said camera.
11. The apparatus according to claim 7 wherein said monitor operates on the PAL system and images produced when each said source is energized are displayed alternately by the scans of said monitor.

12. The apparatus according to claim 7 wherein said monitor operates on the SECAM system and images produced when each said source is energized are displayed by the scans of said monitor.

13. The apparatus according to claim 1 further comprising

   a sleeve disposable about a surgical instrument to be inserted into said region and insertable therewith,

   said sleeve having means for securing said fiber optic light guide to such instrument for insertion into such region with such instrument.

14. An apparatus for reducing the danger of damage to a body member located in a region of an intrusive procedure in a body in which the body member is located comprising,

   a fiber optic light guide insertable into the body member to be protected,

   a source of light energy having means for introducing such energy into said light guide,
said light guide having a region for emitting said infrared energy along axes transverse to said light guide,
a source of visible light,
means for introducing said visible light into said region,
means for pulsing at least one of said sources of light, and
means for locating said body member by detecting said infrared light energy.

15. A sleeve comprising
an elongated hollow body for receiving a surgical instrument to be inserted into a body region to undergo an invasive procedure,
said elongated body having a wall,
an elongated passage extending approximately the length of said hollow body in said wall thereof, and
an optical fiber disposed in said passage in said hollow body.

16. The apparatus according to claim 1 or claim 20 further comprising
means for at least substantially reducing the infrared light energy produced by said visible light source.
17. The apparatus according to claim 4 further comprising
a polarizing filter disposed between said second light guide and said camera.

18. An apparatus for reducing the danger of damage to a body member located in a region of an intrusive procedure in a body in which the body member is located comprising,
a fiber optic light guide insertable into the body member to be protected,
a source of light energy having at least strong infrared light energy,
means for introducing such energy into said light guide,
said light guide having a region for emitting said infrared energy from said body member,
a source of visible light energy,
means for removing a substantial amount of infrared light energy from the visible light,
means for introducing said visible light energy into said region,
a video camera sensitive to both visible and infrared light energy,
said camera supplying signals to said monitor to display signals received by said video camera.
19. An apparatus for reducing the danger of damage to a body member located in a region of an intrusive procedure in a body in which the body member is located comprising,

5 a fiber optic light guide insertable into the body having a member to be protected,

a source of light energy having at least strong infrared light energy,

means for introducing such energy into said light guide,

said light guide having a region for emitting said infrared energy from said body member,

a source of visible light energy,

means for substantially eliminating infrared light energy from said visible light,

means for introducing said visible light energy into said region, and

means for locating the body member by detecting the location of the source of infrared light energy in the body.

20. The apparatus according to claims 18 or 19 wherein

said infrared light energy is pulsed.
21. The apparatus according to claim 19 further comprising means for protecting nerve tissue from damage, said means comprising an infrared light energy probe in contact with the nerve tissue.

22. An article of commerce in kit form comprising a light guide insertable into a cavity in an animal, said light guide having means to emit light from a predetermined region thereof, a source of light having means for directing light into said light guide, a light detector capable of detecting light emitted by said light guide, and said light detector having means for indicating proximity of said means to emit light to said light guide.

23. An article of commerce according to claim 22 further comprising a polarizing light filter.
24. An article of commerce according to claim 22 wherein

suggested source is a source of infrared energy.

25. The method of locating and thus reducing the danger during surgery or other invasion of a body of injury to body members into which a catheter or the like may be inserted comprising the steps of

inserting a catheter into the body member,

inserting an elongated infrared light guide having a region that emits such light into the catheter,

directing infrared light energy into the light guide,

directing visible light into a region adjacent the body member,

pulsing at least one of said lights in alternation, and

indicating the proximity of an ongoing surgical procedure to the body member by determining the intensity of the infrared radiation exiting the body member at the surgical site.
26. The method of locating and thus protecting a body member during a surgical or other body invasive procedure in the vicinity of such body member comprising the steps of emitting infrared energy from the body member to be protected, illuminating the site of the procedure with visible light from which infrared energy has been substantially eliminated, and detecting infrared energy whereby to locate the body member to be detected.

27. The method according to claim 25 further including the step of directing the light energy at the surgical site to a camera sensitive to both infrared and visible light energy.

28. The method according to claim 25 further including the step of polarizing the light presented to the camera.

29. The method according to claim 25 further including protecting a nerve from damage during an invasive body procedure by subjecting the nerve to infrared light energy.
30. The method of locating a body member comprising
   illuminating one side of the body member with infrared light energy, and
   detecting on the opposite side of the body member the location of the source of infrared light energy relative to the body member.

31. An apparatus according to claim 1 further comprising
   means for attaching said fiber optic light guide to said instrument for insertion into such region with such instrument.

32. An apparatus according to claim 19 further comprising
   an audible alarm, and
   means for sounding said audible alarm upon detection of the source of infrared light energy.

33. The method according to claim 30 wherein the body member is a joint of the body, the method of locating a problem in the joint by placing the infrared source on one side of the joint, and
45
detecting the pattern of the infrared
light energy transmitted through the joint on the other
side of the joint.

34. An article of commerce in kit form

5 comprising

a ureteral catheter, and

at least one elongated light guide capable
of transmitting infrared light energy along and
transverse to the length of the light guide.

35. The apparatus according to claim 4 wherein

said probe being disposable in the field
of view of said means for directing light energy to
locate the position of the probe in the operation site.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
   IPC(6) : A61B 6/00
   US CL. : 128/664, 665; 600/135, 182
   According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
   Minimum documentation searched (classification system followed by classification symbols)
   U.S. : 128/664, 665, 899; 600/135, 182

   Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
   NONE

   Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
   NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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<tbody>
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<td>X</td>
<td>US, A, 4,898,175 (NOGUCHI) 06 February 1990, see entire document.</td>
<td>1, 15, 30</td>
</tr>
<tr>
<td>X</td>
<td>US, A, 3,886,933 (MORI ET AL.) 03 June 1975, see entire document.</td>
<td>34</td>
</tr>
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</table>

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
  "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
  "A" document defining the general state of the art which is not considered to be part of particular relevance
  "E" earlier document published on or after the international filing date
  "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
  "O" document referring to an oral disclosure, use, exhibition or other means
  "P" document published prior to the international filing date but later than the priority date claimed

Date of completion of the international search: 03 DECEMBER 1995
Date of mailing of the international search report: 29 DEC 1995

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