



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<b>(21) International Application Number:</b> PCT/US89/00542 <b>(22) International Filing Date:</b> 15 February 1989 (15.02.89) <b>(31) Priority Application Number:</b> 160,007 <b>(32) Priority Date:</b> 24 February 1988 (24.02.88) <b>(33) Priority Country:</b> US  <b>(71) Applicant:</b> REFRACTIVE LASER RESEARCH & DEVELOPMENT PROGRAM, LTD. [US/US]; 7810 Louis Pasteur, San Antonio, TX 78229 (US). <b>(72) Inventors:</b> TABOADA, John ; 12530 Elm Country, San Antonio, TX 78230 (US). POIRIER, Robert, H. ; 3458 River Path, San Antonio, TX 78229 (US).		<b>(74) Agent:</b> LAVINE, Irvin, A.; Mason, Fenwick & Lawrence, 1225 Eye Street, N.W., Suite 1000, Washington, DC 20005 (US).  <b>(81) Designated States:</b> AT (European patent), BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent).  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
<b>(54) Title:</b> METHOD AND APPARATUS FOR CONTROLLING THE DEPTH OF CUT OF A LASER KNIFE		
<b>(57) Abstract</b> <p>An apparatus and method are provided for cutting tissue, such as cornea, to a predetermined depth by an ablative laser. A probe delivers ablative laser energy through coaxial irrigating fluids to cut the tissue, and an optical image of the site is acquired and electronically scanned to produce a voltage analog signal. The laser fire pulse is controlled by a circuit including a first gate controlled by a counter settable to maximum depth of cut and a second gate controlled by signals representing the uncut portion of the tissue.</p> <div data-bbox="949 1227 1372 2049" data-label="Image"> </div>		

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METHOD AND APPARATUS FOR CONTROLLING THE DEPTH OF CUT  
OF A LASER KNIFE

BACKGROUND OF THE INVENTION

5           The present invention relates to a method and apparatus for making cuts by a laser in, particularly, human tissue such as a cornea.

Lasers have been used in the medical field to an ever increasing extent in recent years. In Muckerhide  
10 U.S. Patent 4,316,467, the use of a laser for treating birth marks or lesions on the skin of humans is disclosed, in which control of the power of the laser output energy level is effected by receiving radiation reflected from the lesion by a fiberoptic bundle, the  
15 intensity corresponding with the color intensity of the region at which the laser beam is directed. Through control circuitry, the energy of the laser is varied in accordance with the color intensity of the region being scanned.

20           Goldenberg U.S. Patent 4,641,912 discloses an excimer laser system used for angioplasty, and includes a pair of optical fibers, one for obtaining an image of the atherosclerotic plaque to be ablated by the laser energy, a second optical fiber being provided for  
25 lasing the plaque. A video camera and monitor are utilized to display an image of the plaque.

Karlin et al U.S. Patent 4,583,539 discloses a system for performing surgery on the eye using a CO<sub>2</sub> laser source and an articulated arm structure, the  
30 laser energy being delivered through a probe which is connected to the articulated arm structure and which is insertable into an eye.

Kimura U.S. Patent 4,266,549 discloses a laser scalpel including a probe through which light may be  
35 directed to illuminate the optical site: where a tumor is to be subjected to lasing, a picture or graphic

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representation may be obtained. An adaptor is provided at the tip of the probe to engage the tissue at or adjacent the tumor, to establish the distance of the focussing lens of the probe to the tumor to be lased.

5 Remy et al U.S. Patent 4,289,378 discloses an apparatus for adjusting the focal point of a working laser beam onto a microscopic target region of a transparent biological object. Use is made of an auxiliary laser beam having a wavelength within the  
10 visible range, and through joint focussing of the laser beams, the location of focussing of the working beam at a particular locus at a desired depth within the transparent biological specimen is achieved.

#### SUMMARY OF THE INVENTION

15 A laser knife method and apparatus are provided in which an ablative laser source is provided with a fire pulse controller. A probe receives and directs a laser beam to transparent tissue, such as a cornea, to make a cut which extends only a part way through the cornea.  
20 The probe has apparatus to generate an optical transverse representation of the cornea and the cut in it, including a light source for delivering light to the tissue, a reflector for the image, and a lens for delivering the optical representation of the tissue and  
25 cut to an optical fiber bundle. The optical representation has a relatively high degree of illumination in that part of the image corresponding to the uncut portion of the cornea, while the cut portion of the cornea has a relatively lower level, or no,  
30 illumination. The optical image representation is delivered to an electronic scanner which emits pulses having voltages proportional to the intensity of the light at incremental locations along the optical image. The emitted pulses are delivered to an  
35 amplitude threshold detector which emits pulses when the received pulses are at a suitably high voltage,

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indicative of the uncut portion of the cornea. A clock drives the scanner and a down counting manually settable counter, and signals from the clock are delivered sequentially to a first gate and a second gate. The first gate receives an end-of-count signal from the counter, so as to enable the gate to pass the clock pulses when the depth of cut has not exceeded the set depth. The signals from the amplitude threshold detector are delivered to the second gate, so as to enable the second gate to pass the clock signals to the laser fire pulse controller only when the laser beam, upon firing, will strike an uncut portion of the tissue. When both gates are enabled, pulses pass to the laser fire pulse controller through a manually operable switch.

An object of the present invention is to provide an ablative laser knife apparatus and method for controlling the depth of cut of transparent tissue.

Another object of the invention is to provide an apparatus and method for cutting into transparent tissue without exceeding a predetermined depth of cut.

Still another object of the present invention is the provision of an apparatus and method for controlling the depth to which a cut in transparent tissue may be made, and for adjusting the maximum depth of cut.

Yet another object is the provision of a laser knife method and apparatus and control circuitry for preventing the firing of the laser unless the laser beam will strike only tissue which was not previously cut.

Other objects and many of the advantages of the present apparatus and method will be readily understood from the following specification and claims, and consideration of the appended drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

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Fig. 1 is a schematic view of a laser knife depth of cut apparatus in accordance with the present invention.

Fig. 2 is an elevational view, partly in section, of a portion of a probe forming a part of the apparatus of Fig. 1.

Fig. 3 is a view taken on the line 3-3 of Fig. 2.

Fig. 4 is a schematic view of an optical scanner and related elements forming a part of the apparatus of Fig. 1.

Fig. 5 is a chart illustrating an optical image obtained of an uncut cornea by the probe of Fig. 2 and a corresponding voltage output.

Fig. 6 is a view similar to Fig. 5, and showing an optical image of a cut cornea.

Fig. 7 is a diagram of a circuit forming a part of the apparatus of Fig. 1, and related elements.

#### DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings, wherein like or corresponding reference numerals are used to designate like or corresponding parts throughout the several views, there is shown in Fig. 1 an apparatus generally designated 10 for cutting transparent material, such as tissue, and more particularly cornea, by a laser, and for limiting the depth of cut, ensuring that the laser is operative only to strike tissue when fired. There is shown an ablative laser 12, such as an excimer type, controlled by a laser fire pulse controller 13. The beam of laser 12 is delivered to an articulated arm system 14, comprising jointed, hollow arms and reflectors or refractors. A probe 15 receives the laser beam from the articulated arm system 14 and directs it to the transparent tissue to be cut. The probe 15 includes an annular optical element 16 which forms a part of the probe 15, and receives light from light source 17 through an optical fiber 18. An

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optical image is acquired by a fiberoptic bundle 19 and is delivered to a signal converting and emitting apparatus 20. Emitted signals are carried by a conductor 21, when manually operated switch 22 is closed, to the laser fire pulse controller 13 to fire the laser 12.

In Fig. 2, there is shown the probe 15 in cross-section, probe 15 comprising a thin hollow tube 25 having at or near the upper end a focussing lens 26 sealed to it by a wall 27. Lens 26 receives and focuses the laser beam 28 from the laser 12. A conduit 29 is fluid connected to the tube 25, to introduce a body of liquid, such as normal saline solution, into the tube 25, through which the laser beam 28 passes.

At its lower end, tube 25 has attached to it the annular transparent optical element 16 which comprises an annular flange 31 that receives the end of tube 25 and is securely attached to it. The annular configuration of transparent optical element 16 provides a passage 32 which forms an extension of the fluid passage provided by the interior diameter of tube 25. The annular optical element 16 also comprises an upwardly facing horizontal surface 33 and an inclined reflecting surface 34.

As shown in Fig. 3, the bottom surface 36 of optical element 16 is provided with a plurality of radial grooves 37 to permit the efflux of normal saline solution which has passed downwardly through the tube 25 from conduit 29, thus washing out debris. The bottom contact surface 36 and the cylindrical and conical surfaces of optical element 16 are polished optically clear. The single fiber light conductor 18 is shown and the fiberoptic bundle 19, each extending, for convenience, at least partly along the length of the tube 25.

The bottom surface 36 of the optical element 16 is

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in engagement with the upper surface of a cornea C, which is a transparent organic tissue. As shown in Fig. 2, the laser beam 28 passes through the body of liquid which extends to the treatment site, i.e., the cornea C, and is focussed at a point P, and thereby has made a cut into the cornea C to the depth indicated by point P.

Light passing through the single optical fiber 18 will strike the upper surface 33 of optical element 16 and pass into it, the light being emitted from the bottom surface 36 and illuminating the cornea C. Light will pass through cornea C where it has not been cut, that is, below the point P. Above the point P, where there has been a cut, the light will not pass, or will pass to a greatly diminished extent. An image of the cornea C in the region of the cut will be passed into the optical element 16 as indicated by ray 38, and will be reflected from the reflecting surface 34 through the upwardly facing surface 33, where the image of the cornea C at a plane through the penetration point P, having been acquired through the total internal reflection at the inclined reflecting wall 34, passes through the surface 33 to a coupling lens 39 which focusses the image onto the fine coherent fiberoptic bundle 19. Coupling lens 39 may be a narrow graded index rod lens such as a Selfoc lens produced by N.G.S. America, Inc.

Fig. 4 is a diagrammatic illustration of a part of the signal converting and emitting apparatus 20. There is shown in Fig. 4 the end of the fiberoptic bundle 19 which projects the image formed by the ray 38 through a projection lens 41 and to a half-reflecting mirror 42, or the equivalent, where the image being projected onto a photodiode array scanner 45. The image of the cornea may also be acquired by a video camera 43, and pass to a display monitor (not shown) for viewing.



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The photodiode array scanner 45 may be a solid state line scanner, such as the EG&G Reticon G-Series solid state line scanner, which includes photodiode elements which emit signals proportional to the intensity of the light striking them, and which are serially scanned by a photodiode array scan controller 46, the latter including a start gate 47 for receiving a start signal, a clock gate 48 for receiving a clock signal, an output gate 49 for emitting an output or video signal, and a gate 51 for emitting an end of scan signal.

The image of the cornea C is shown by line 52, which represents the inner edge or surface of the cornea, and by the line 53, which represents the outer edge or surface of the cornea C. The line 54 is the demarcation line between the cut and uncut portions of the cornea C, so that the distance between the lines 53 and 54 represents the depth of cut, shown in Fig. 4 as being approximately three-fourths through the thickness of the cornea C, that is, three-fourths of the way between the outer edge or surface represented by line 53 and the inner edge or surface represented by line 54. As will be apparent, the photodiodes on the photodiode array 45 which are between the lines 52 and 54 will receive a relatively high degree of illumination, and will thereby emit relatively high voltage signals, whereas those photodiodes between the lines 53 and 54 will receive very low or no significant illumination since they will, in effect, be exposed to the image of the cut, non-transparent portion of the cornea and will emit low voltage video signals. The photodiodes will emit the noted signals when scanned under the direction of controller 46. The photodiode scan controller 46 is actuated by a start signal from a clock (discussed hereinbelow) which enters the clock gate 48.

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Fig. 5 is a representation of an image obtained by the probe and related apparatus of Fig. 2, as well as the output of the photodiode array 45. Distance, or depth of the cornea C is indicated along the ordinate, and light intensity along the abscissa. Within the curved line, therefore, it will be seen that for a substantial depth, there is a relatively high light intensity. When this optical image is converted by the photodiode array 45 and the scan controller 46, the ordinate will represent time, proportional to distance, due to the action of a clock, and the abscissa will represent voltage, due to the nature of the output of the photodiodes of the photodiode array 45, as above explained. In this case, all of the photodiodes will be producing a high voltage, because of the above noted high intensity level of the illumination, from light which has traversed the uncut cornea C. Fig. 6 illustrates the same relationships, after the cornea C has been cut partially through its depth or thickness; the dash lines represent the original corneal outer edge or surface, and the solid lines represent the corneal depth after the cornea has been partially cut through by the laser knife, as indicated by the solid line. In this case, the upper generally horizontal part of the solid line represents the upper edge of the cornea with a cut therein, and, simultaneously, the bottom edge of the cut in the cornea.

Referring now to Fig. 7, there is shown a block diagram of the signal converting and emitting apparatus 20 and certain related elements. A clock 60 emits pulses to a photodiode array controller 46, to manually settable, down-counting counter 61, to gate A and to gate C. Preset counter 61 includes a manual set apparatus 61a.

Photodiode array controller 46 emits a video signal V as the photodiode array 45 is caused to scan

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the image of the cornea C. Signal V, as above indicated, comprises a series of high voltage pulses in response to illumination through the uncut portion of the cornea, and lower voltage pulses in response to  
5 illumination received from the cut portion of the cornea. This signal V drives an amplitude threshold detector 62, which emits a threshold exceed signal during the time that it receives the higher voltage pulses from the photodiode array controller 46. These  
10 threshold exceed signals are provided to gate B and gate C. The photodiode array controller 46 also emits an end-of-scan signal which enters the start gate 47 to recycle the photodiode array controller 46, and which resets the counter 61. Consequently, since the clock  
15 60 drives the photodiode array controller 46 at a constant rate and since the photodiode array controller 46 is continuously recycled by the end-of-scan signal so that it successively scans the received image of the cornea, the effect is that the time elapsed is  
20 representative of a length, in this case, the thickness of the cornea.

When the preset counter 61 emits its end-of-count signal, it opens or enables gate A, thereby ensuring that the clock pulses are not passed to gate B unless  
25 the actual depth of cut is less than the preset depth of cut. That is, the end-of-count signal from the manually set, down-counting counter 61 determines the maximum depth of cut of the cornea and will not permit the firing of the laser to cut the cornea to a greater  
30 depth than the preset depth.

Gate B is enabled by threshold exceed signals TE from the amplitude threshold detector 62, so as to pass clock pulses received from gate A to the laser fire pulse controller 13 through the manually operated  
35 switch 22. Thus, gate B is enabled only when pulses from the laser 12 (Fig. 1) will strike an uncut portion

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of the cornea C.

Gate C, which receives pulses from clock 60 and threshold exceed signals TE from the amplitude threshold detector 62, will be enabled by threshold exceed signals TE, and permit clock pulses to pass to a display counter 63, which also receives reset signals, which are the end-of-scan signals from the photodiode array controller 46. This display counter 63 enables the operator to determine the thickness of the cornea C at the point of contact by the probe 15 prior to the beginning of a cut in the cornea C. The display counter 63 counts clock pulses that are received when the gate C is enabled. When an uncut cornea, see Fig. 5, is scanned by probe 15, all of the signals V from photodiode array controller will be high voltage signals, and thus all of them will result in the emission of threshold exceed signals TE from the amplitude threshold detector 62, resulting in the enabling of gate C during a maximum portion of the scan period, since there are no uncut portions scanned and therefore no low voltage signals emitted. Where there has been made a cut in the cornea C to a certain depth, as illustrated in Fig. 6, the display counter 63 will provide an indication or measure of the uncut depth illustrated by the solid line, and thereby enable the operator, if a deeper cut is desired, to adjust the manual set apparatus 61a.

There has been provided a laser knife apparatus and method in which depth of cut of transparent material or tissue, such as cornea, may be accurately controlled, with safeguarding against exceeding a predetermined depth of cut and directing laser energy into a portion of the cornea which has already been cut, so that the laser beam is focussed only onto uncut cornea portions. Further, the apparatus and method herein disclosed provide for both observation of the

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depth of cut and for adjusting the maximum depth of cut. The apparatus herein provided is readily assembled from existing components, or with modification thereof which require minimal expenditure.

5       It will be obvious to one skilled in the art that various changes may be made without departure from the spirit or scope of the invention, and therefore the invention is not limited to that shown in the drawings, and described in the specification, but only as  
10 indicated in the appended claims.

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WHAT IS CLAIMED IS:

1. Apparatus for making cuts in light permeable material to a preselected depth comprising:

(a) an ablative laser for generating pulses for causing cuts in said material,

(b) means for generating an optical representation of the depth of a cut in said material,

(c) means for receiving said optical representation and for generating analog signals representative of the depth of cut,

(d) means connected to said laser for firing said laser, and

(e) means for controlling said laser firing means comprising

(i) enabling means for permitting firing of said laser only when the depth of cut is less than a limiting value, and

(ii) enabling means for permitting firing of said laser only when firing will cause laser radiation to strike uncut material.

2. The apparatus of claim 1, wherein said optical representation generating means comprises

means for illuminating material on one side of a cut made by said laser,

means for receiving a representation of the material and the cut therein.

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3. The apparatus of claim 2, wherein said means for illuminating said material comprises an annular, transparent optical element having an inclined reflecting surface, a collecting lens for receiving an optical representation of said material and the cut therein, and a fiberoptic bundle positioned to receive an image transmitted by said collecting lens.

4. The apparatus of claim 2, said illuminating means comprising fiberoptic means directed to said annular optical element, and positioned remotely from said collecting lens.

5. The apparatus of claim 1, wherein said means for receiving said optical representation and for generating analog signals representative of the depth of cut comprises:

an optical scanner having a video signal output,  
and

an amplitude threshold detector for detecting video signals which indicate a portion of the thickness of said material which has not been cut by said laser, and for transmitting a threshold exceed signal therefrom.

6. The apparatus of claim 5, wherein said scanner comprises a photo diode array controller.

7. The apparatus of claim 1, said laser firing controlling means further comprising a clock connected to said laser firing means through both of said enabling means.

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8. The apparatus of claim 7, said means for controlling said laser firing means further comprising a manually settable counter, means for delivering signals from said clock to said counter, and means for delivering end of count signals from said counter to said first mentioned enabling means.

9. The apparatus of claim 8, wherein said means for receiving said optical representation and for generating analog signals representative of depth of cut comprises an optical scanner having a video signal output, and wherein said second mentioned enabling means comprises an amplitude threshold detector for receiving said signals from said scanner and for generating signals only when said scanner emits signals representative of the uncut portion of said material, said second mentioned enabling means comprising a gate enabled by the signals from said amplitude threshold detector.

10. The apparatus of claim 9, said clock being connected to said photodiode array controller, said photodiode array controller emitting an end of scan signal.



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11. Apparatus for making cuts in light permeable material to a preselected depth comprising:

(a) an ablative laser for generating pulses for causing cuts in said material,

(b) means for maintaining a body of liquid adjacent the material being treated,

(c) means for passing ablative laser beams from said laser through said liquid,

(d) means for generating an optical representation of the depth of a cut in said material,

(e) means for receiving said optical representation and for generating analog signals representative of the depth of cut,

(f) means connected to said laser for firing said laser, and

(g) means for controlling said laser firing means comprising

(i) enabling means for permitting firing of said laser only when the depth of cut is less than a limiting value, and

(ii) enabling means for permitting firing of said laser only when firing will cause laser radiation to strike uncut material.

12. The apparatus of claim 11, wherein said light permeable material is a cornea, said apparatus further comprising means for causing at least part of said liquid to flow past said cornea, and means for introducing additional liquid into said body of liquid.

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13. Method of making cuts in transparent material to a predetermined depth comprising:

aiming an ablative laser beam to material to be cut,

sensing the depth of any cut in said material, and limiting the focussing of a laser beam to an uncut portion of the material which is at a lesser depth than a preselected depth.

14. The method of claim 13, wherein said determination of the depth of cut is by the acquiring of an optical image of the material transverse to a cut therein at the locus of the cut.

15. The method of claim 14, said method further comprising providing an electrical analog signal of said optical representation, and wherein said laser is permitted to be fired only when said electrical analog signal indicates both an uncut portion of said material and that any cut portion has been cut to a depth less than a predetermined depth.

16. The method of claim 13, and further comprising providing a body of liquid in contact with the material, and wherein said ablative laser beam is passed through said liquid to said material to be cut.

17. The method of claim 16, said material being human tissue, and said liquid being clear irrigating fluid.

FIG. 1

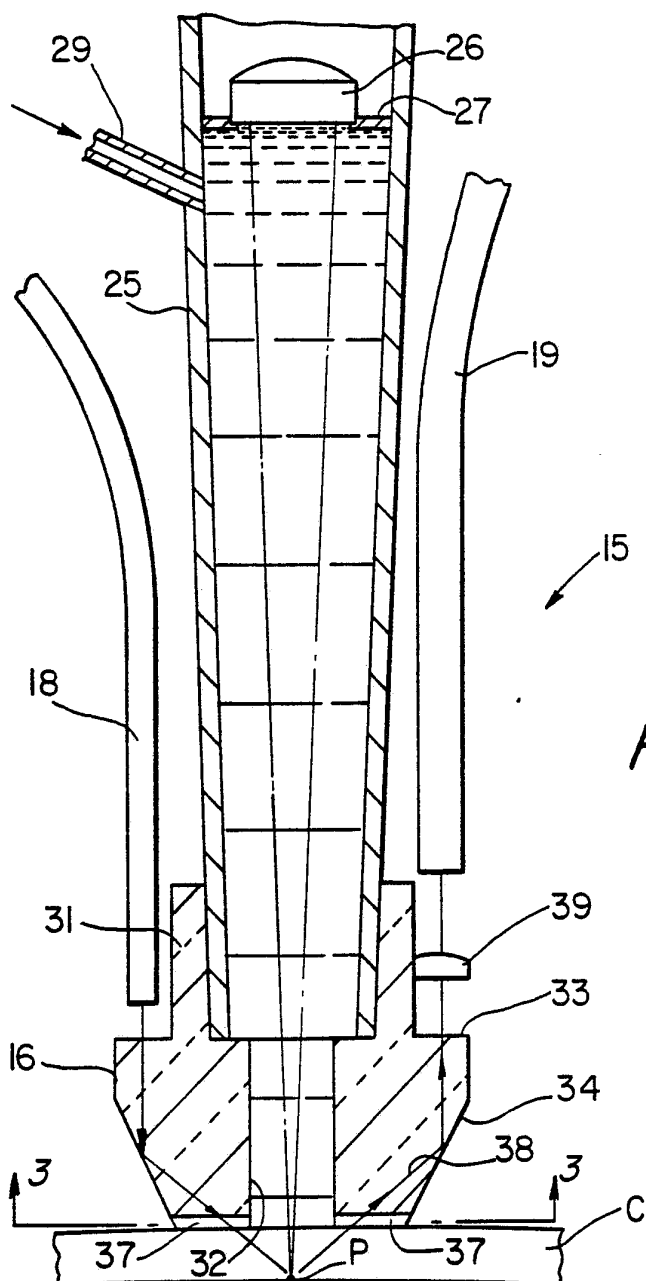
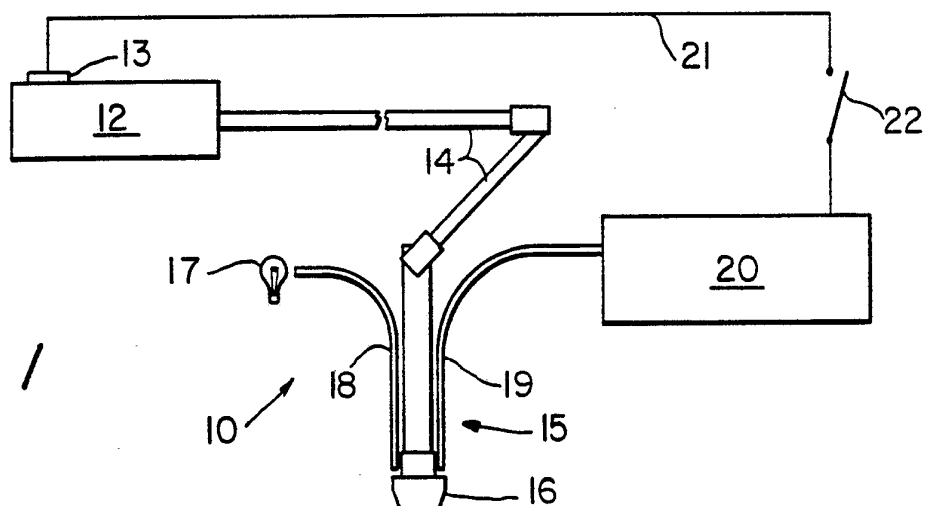


FIG. 2

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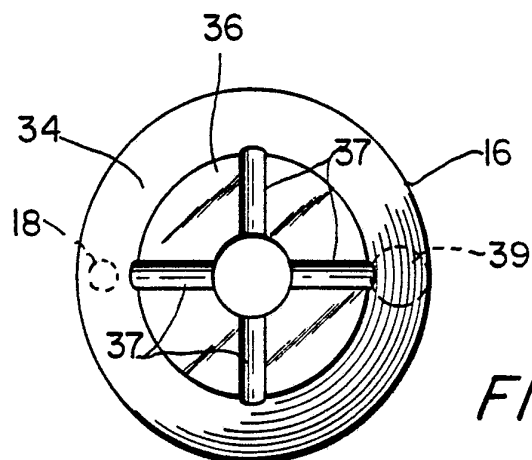


FIG. 3

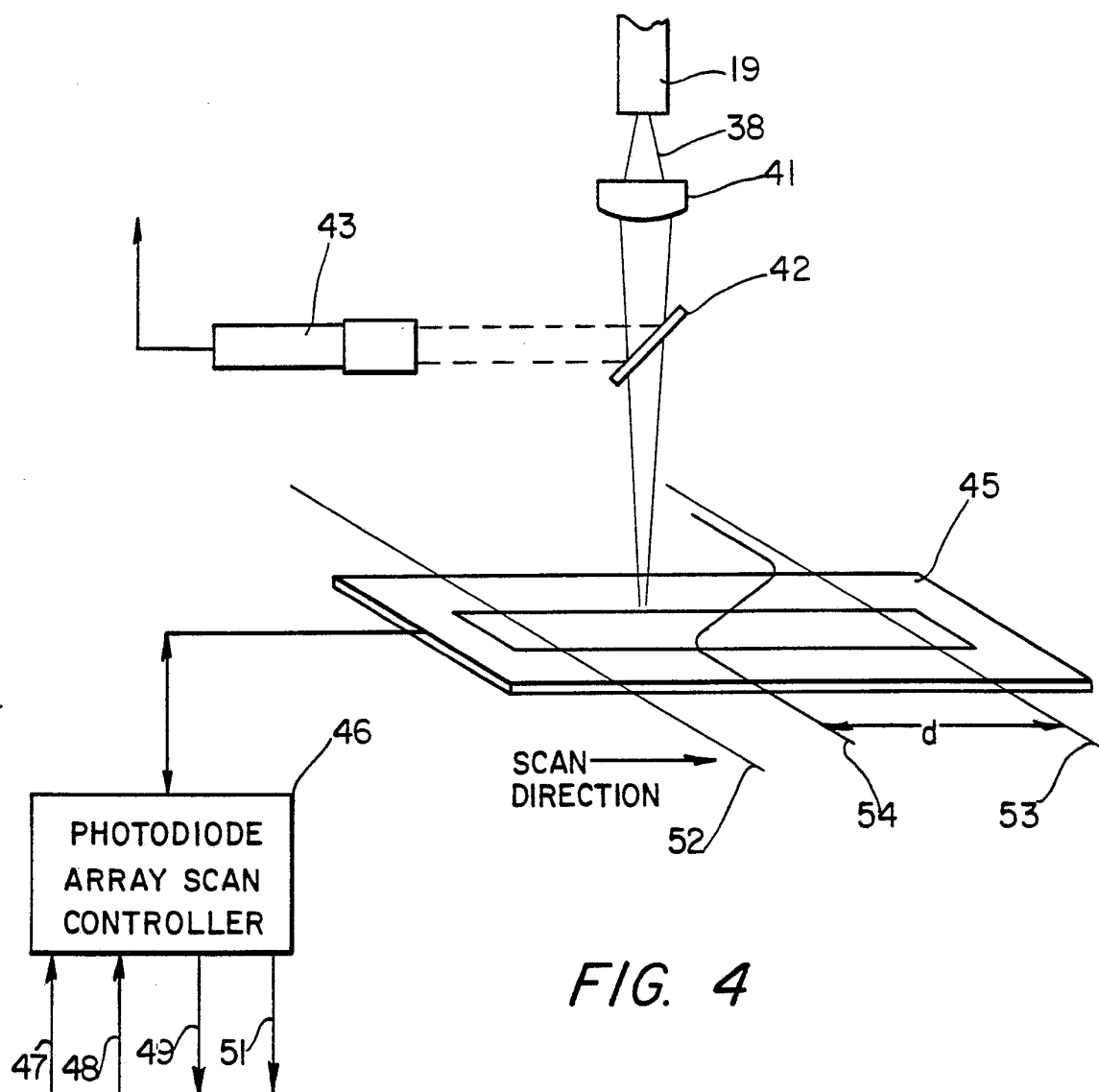


FIG. 4

- 3 / 3 -

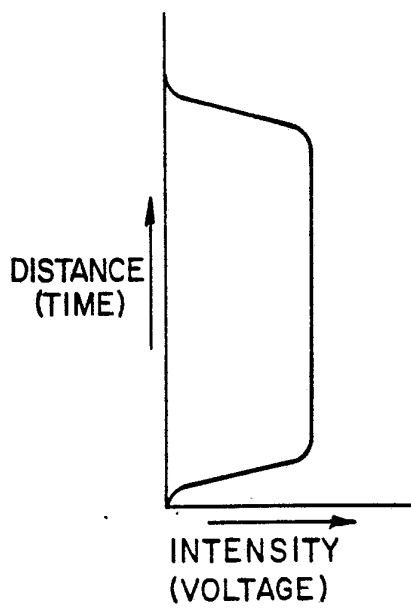


FIG. 5

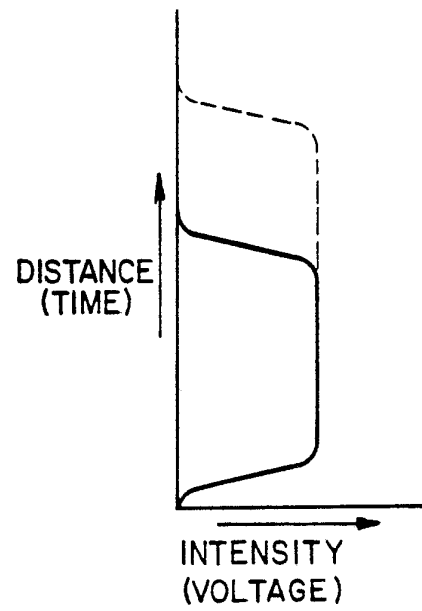


FIG. 6

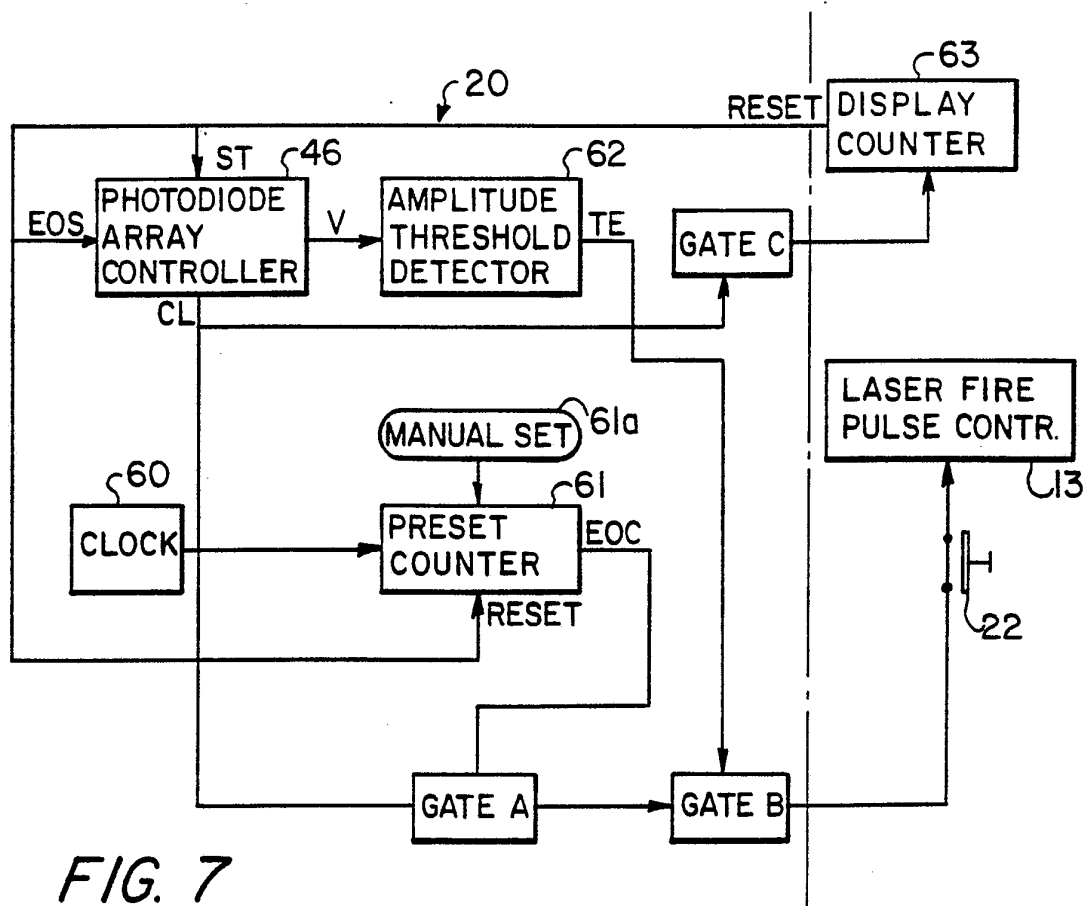
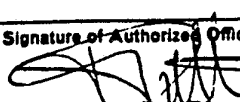


FIG. 7

# INTERNATIONAL SEARCH REPORT

International Application No PCT/US 89/00542

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (if several classification symbols apply, indicate all) <sup>6</sup>		
According to International Patent Classification (IPC) or to both National Classification and IPC IPC <sup>4</sup> : A 61 F 9/00, B 23 K 26/04, A 61 B 17/36		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched <sup>7</sup>		
Classification System	Classification Symbols	
IPC <sup>4</sup>	A 61 F, A 61 B, B 23 K, G 01 B	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched <sup>8</sup>		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT <sup>9</sup></b>		
Category <sup>10</sup>	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>	Relevant to Claim No. <sup>13</sup>
A	WO, A, 87/01272 (BERKMAN et al.) 12 March 1987, see page 5, line 33 - page 6, line 2; page 11, lines 3-8, 25-30 --	1
A	EP, A, 0222537 (YORK) 20 May 1987 --	
A	EP, A, 0255581 (BELGOROD) 10 February 1988 --	
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A	Patent Abstracts of Japan, vol. 10, no. 295 (M-523)(2351), 7 October 1986 & JP, A, 61108484 (MITSUBISHI ELECTRIC CORP.) 27 May 1986	
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<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search		Date of Mailing of this International Search Report
23rd June 1989		19 JUL 1989
International Searching Authority		Signature of Authorized Officer
EUROPEAN PATENT OFFICE		 P.C.G. VAN DER PUTTEN

**ANNEX TO THE INTERNATIONAL SEARCH REPORT  
ON INTERNATIONAL PATENT APPLICATION NO.**

US 8900542  
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The members are as contained in the European Patent Office EDP file on 11/07/89  
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		AU-A- 6334186	24-03-87
		EP-A- 0235260	09-09-87
		JP-T- 63500645	10-03-88
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		JP-A- 62298355	25-12-87
US-A- 4705037	10-11-87	None	
US-A- 4555179	26-11-85	None	
US-A- 4588885	13-05-86	US-A- 4737628	12-04-88
DE-A- 3245846	14-07-83	JP-A- 58143745	26-08-83
		JP-A- 58116350	11-07-83
		US-A- 4622971	18-11-86
EP-A- 0123548	31-10-84	US-A- 4468197	28-08-84