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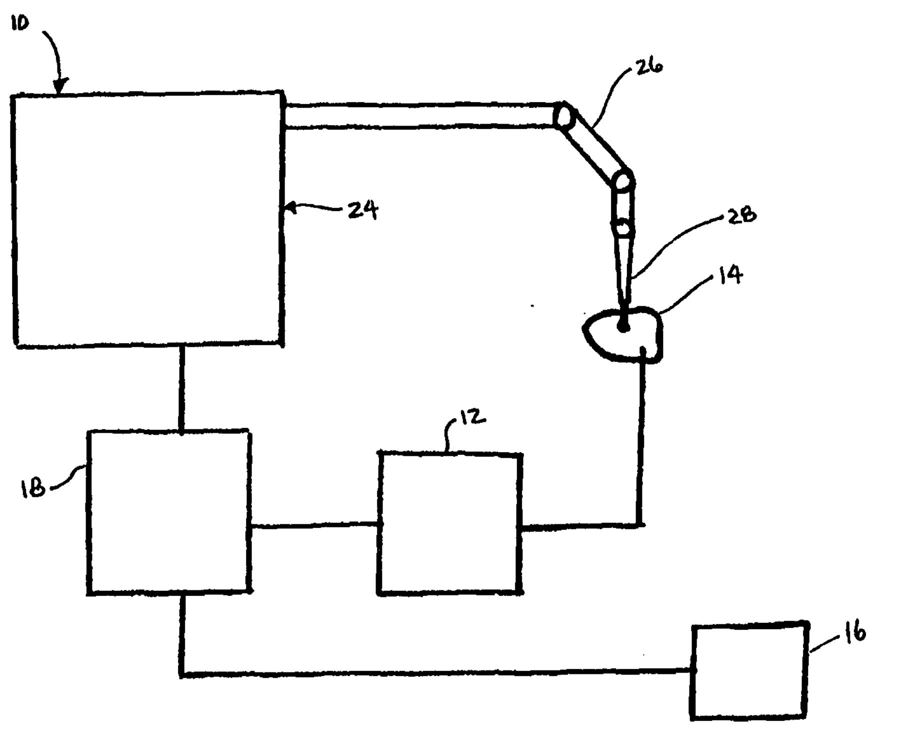

(57) Abstract

This invention is a high–energy, short pulsed laser system (10), and method for performing transmyocardial revascularization. The laser system (10) applies a single laser pulse in one millisecond to produce a revascularizing channel completely through the myocardium.

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TRANSMYOCARDIAL REVASCULARIZATION LASER SYSTEM

FIELD OF THE INVENTION

The present invention is a medical laser system for treating ischemia with transmyocardial revascularization.

BACKGROUND OF THE INVENTION

As is well known, the heart has four chambers for receiving and pumping blood to various parts of the body. During normal operation of the heart, oxygen-poor blood returning from the body enters the right atrium. The right atrium fills with blood and eventually contracts to expel the blood through the tricuspid valve to the right ventricle. Contraction of the right ventricle ejects the blood in a pulse-like manner into the pulmonary artery and each lung. The oxygenated blood leaves the lungs through the pulmonary veins and fills the left atrium. The left atrium fills with blood and eventually contracts to expel the blood through the mitral valve to the left ventricle. Contraction of the left ventricle forces blood through the aorta to eventually deliver tne oxygenated blood to the rest of the body. The heart muscle receives its blood supply from the coronary arteries, which feed out and around onto the outside of the heart muscle.

The laser has developed into a very useful tool in modern surgery because of its pinpoint accuracy. With the introduction of carbon dioxide laser systems with 25 to 1000 watts of continuous power output, the carbon dioxide laser has been used for excision and vaporization of tissue in neurosurgery and plastic surgery as well as gastroenterology, urology, otolaryngology, gynecology and, most recently, in cardiac applications.

Lasers have recently been shown to be useful in transmyocardial revascularization. Transmyocardial revascularization is a method for treating ischemic heart disease. Heart disease is the leading cause of disability and death in all industrialized nations, accounting for nearly twice as many deaths as those resulting from cancer. The majority of these deaths are due to coronary artery disease, a condition which results in the heart muscle (or myocardium) not receiving an adequate nutritive blood supply. Transmyocardial revascularization is a technique used to supplement the blood supply delivered to the heart by providing the ischemic myocardium direct access to blood within the ventricular chamber. Normally the myocardium does not have direct access to the ventricular chamber and receives its nutritive blood supply entirely from the coronary arteries branching through the heart wall. The additional blood flow provided by the transmyocardial revascularization makes up for the reduced blood flow from the coronary arteries and relieves the ischemia.

In the procedure known as transmyocardial revascularization (TMR), a laser is used to create holes or channels through the myocardium to provide an alternate blood supply to the heart muscle in patients with severe coronary artery disease. See U.S. Patent Nos. 5,125,926 and 5,554,152 for example. Most of the studies to date have used a continuous wave (CW), carbon dioxide (CO_2) laser to create the holes by ablation of the tissue in the beam path. In order to apply sufficient laser beam energy to completely penetrate the heart wall, a 800 watt laser is turned on for a time period of about 40 to 50 milliseconds, which provides about 30 to 40 joules. Considerable success has been seen clinically with this procedure, particularly in the reduction of angina pain. Laser implemented transmyocardial revascularization shows great promise for heart patients, but it does have some medical obstacles associated with it. The thermal time constant of the tissues in the myocardium is of the order of a few milliseconds. Therefore a laser pulse as long as 40 to 50 milliseconds will produce considerable heating of the surrounding tissue. A number of studies show that, due to the healing of the thermally damaged tissue and subsequent scar formation, many of the holes close up either partially or completely, and thus can provide only a small amount of additional blood flow to the capillary system of the myocardium.

In order to drill a straight, uniform hole through the heart wall while the heart is beating, the motion of the heart wall must be essentially zero for the duration of the pulse. For a laser pulse 50 milliseconds long, there is only one period during the heart cycle when the heart wall is at rest for a time of that extent, this is between the end of diastole and the beginning of systole. At this short period, the motion is minimal when the fully expanded ventricles are waiting for the depolarization of the cells which initiates the contraction process. The length of this resting period varies with the pulse rate of the individual and can be significantly less than 50 milliseconds for some patients, resulting in less laser energy available and the possibility of incomplete penetration of the laser beam.

Other lasers being used for transmyocardial revascularization, such as Holmium:YAG or excimer lasers, do not produce sufficient energy to fully penetrate the myocardium in one heart cycle. Due to the long time required to create the channel, and in the case of the Holmium:YAG laser a relatively low absorption in the tissue, the thermal damage to adjacent tissue is quite high. The subsequent healing process then tends to close the channels as described above.

SUMMARY OF THE INVENTION

The system of the present invention produces optimized channels resulting in maximum reperfusion of blood into the myocardium and greatly increasing the success of the TMR procedure. Optimized channels means channels or holes through the heart wall during the creation of which there is much less thermal damage to the surrounding tissue. Minimizing thermal damage to the surrounding tissue results in a more benign healing process in which there is minimal closure of the channels due to scar formation. The more benign healing process preserves the structural integrity of the adjacent tissue and provides a less thrombogenic surface. Channels which stay open more consistently and more uniformly will provide a much greater auxiliary blood flow to the treated regions of the myocardium.

A second possible source of additional blood flow is by means of the growth of new blood vessels in the vicinity of the channel during the healing, a process known as angiogenesis. The ability of these new blood vessels to relieve ischemia depends upon their forming interconnections to the collateral artery system of the heart. If the channel is surrounded by a large, heavily fibrotic scar tissue layer, these vessels tend to terminate in the scar. Therefore, creating the channels with minimal thermal damage, and subsequent minimal scar formation, will enhance the contribution of angiogenesis to the new blood flow resulting from the TMR procedure.

A laser pulse on the order of about 1 millisecond in accordance with the present invention produces very little heating of, and consequent damage to, adjacent tissue because the laser energy is applied in a time which is shorter than the thermal diffusion time in the tissue. During the applied laser pulse, the heat generated by the laser does not have enough time to flow out of the tissue being vaporized into the adjacent tissue thus minimizing or eliminating thermal damage to the adjacent tissue. Also if the wavelength of the laser is such that the absorption of the laser energy is at the surface, then there is no direct heating of the adjacent tissue by the incident laser radiation. The present system utilizes a high-energy, short-pulsed laser operating at a wavelength which is highly absorbed at the surface of, and in the myocardial tissue. The consequences of such a system are channels formed which provide the following: 1) preservation of the integrity of the surrounding tissue, 2) a more benign healing process resulting in minimal fibrosis and scarring, and 3) a less thrombogenic surface. All of these contribute to a process which provides for greater additional blood flow to the ischemic myocardium.

The high energy, short-pulsed laser system of the present invention can be synchronized to the heart's beating cycle to apply the laser pulse when the patient's ventricle is at or near full contraction such that the subsequent expansion phase of the heart's beating cycle keeps the lazed holes open mechanically at full diameter to prevent partial closing off of the holes and clotting. Because the heart wall is in motion throughout the contraction, the laser energy is delivered in about 1 millisecond so that the heart wall is effectively stationary relative to the pulse and uniform, straight holes are created through the heart wall.

In one aspect of the present invention, there is provided a laser system for performing transmyocardial revascularization on a beating heart which comprises a laser having a beam operating at a wavelength with very high absorption in myocardial tissue with about a one millimeter diameter, means for directing the laser at a wall of the beating heart, and means for emitting the beam at the wall of the beating heart for about one millisecond to create a revascularizing channel completely through the wall in the about one millisecond.

In another aspect, there is provided a method for myocardial revascularization of a beating heart which comprises emitting laser energy with a beam having about a one millimeter diameter operating at a wavelength with very high absorption in myocardial tissue at a wall of the beating heart, and creating a revascularizing channel completely through the wall of the beating heart within five milliseconds or less with the beam.

In yet another aspect, there is provided a method for myocardial revascularization of a beating heart which comprises emitting a single, one millisecond laser pulse with a beam operating at a wavelength with very high absorption in myocardial tissue at a wall of the beating heart, and creating a revascularizing channel having about a one millimeter diameter completely through the wall of the beating heart with the single, one millisecond laser pulse.

BRIEF DESCRIPTION OF THE DRAWINGS

As used herein, like reference numerals will designate similar elements in the various embodiments of the present invention wherein:

FIG. 1 is a schematic block diagram of a heart-synchronized high-energy, short-pulsed laser system according to the present invention; and

FIG. 2 illustrates the ECG signal and a firing pulse period in accordance with the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

There is shown in FIG. 1 a heart-synchronized, high energy, short-pulsed laser system 10 with electrocardiogram (ECG) unit 12 connected to a heart 14 which is to undergo the surgery. The ECG signal is delivered to trigger circuit 18, which provides a trigger pulse to laser unit 24 including a laser power supply and a high-energy, short-pulsed laser to produce a pulsed laser beam through articulating beam delivery optical arm or flexible waveguide 26 into optical handpiece 28 to make holes or channels in heart 14. A number of channels can be formed from the outer wall (epicardium) extending through the myocardium and perforating the interior of the heart wall (endocardium). The position of the trigger pulse in the heartbeat cycle is determined by trigger circuit 18. The high energy, short-pulsed laser produces short pulses of energies in the range of about 5 to about 30 joules. The delivered laser energy is between about 5 to about 30 joules according to the thickness of the myocardium as previously mapped by echocardiography. The beam quality is sufficiently high to allow the output beam to be focused to a 1 millimeter diameter with a depth of field of at least about 20 millimeters. The duration of the laser pulse is fixed (i.e., every laser pulse has the same duration) at about 5 milliseconds or less, preferably fixed at about 2 milliseconds or less, most preferably fixed at about 1 millisecond or less. A high energy, short-pulsed CO_2 laser operating over the range of 9.5 to 10.8 micrometers, preferably at 10.6 micrometers (such as available from Pulse Systems, Inc., Los Alamos, New Mexico) is used that creates complete holes through the myocardium with a single laser pulse, although depending on the resolution used to analyze the pulse, the pulse may appear as a series of micropulses within the single pulse. The amount of energy delivered to the heart tissue is independent of pulse duration. The laser energy is applied in a time which is shorter than the thermal diffusion time of the heart tissue so that the heat generated during the ablation of the heart tissue in the hole will not have time to flow out of the tissue being vaporized during the applied laser pulse to the surrounding tissue.

Trigger circuit 18 may be included as an additional board in a personal computer or a microprocessor controller, in which case the system can be controlled through the computer keyboard and suitable software or custom control panel. The microprocessor controller and ECG unit 12 may have separate monitors, or they may have a single monitor which displays both the ECG and information about the laser system 10. Trigger circuit 18 includes a gate which generally inhibits the delivery of a trigger pulse to laser unit 24. The inhibiting effect of this gate can be overcome when the surgeon steps on foot switch 16.

The heart cycle can be described in terms of the signals seen by an electrocardiograph (ECG) 21 as shown in Figure 2. The volume curve 22 of the left ventricle showing the expansion and contraction of the heart is also shown. The impulse to begin a heart cycle starts at the sinus node and first triggers the activation of the atria, this is represented by the normal P wave of the electrocardiogram. At some time later (approximately 160 milliseconds), near the end of the P wave, the impulse reaches the atrioventricular (AV) node and subsequently the ventricular myocardium which then triggers the ventricular contraction. The onset of ventricular depolarization is represented by the beginning of the normal Q wave. The QRS complex, that is, the combined Q, R and S waves, represents the sequence of ventricular depolarization, and is approximately 80 milliseconds in duration. The ventricular contraction begins at the end of the S wave and continues for approximately 420 milliseconds to the end of the normal T wave. The T wave represents the ventricular repolarization. Diastole is the period from the end of the T wave to the beginning of the Q wave (i.e., the period during which the ventricles expand to full volume and fill until the signal to begin the next contraction starts). Systole is the period from the beginning of the QRS complex to the end of the T wave (i.e., when the ventricles undergo depolarization, contraction, ejection, and repolarization).

With a laser pulse rate on the order of about 5 milliseconds or less in accordance with the present invention, the laser pulse can be fired at anytime during the heart cycle and the relative wall motion during the pulse is negligible. Therefore, the present invention has the flexibility of firing at any time during the heartbeat cycle to achieve a high quality, optimized hole. It is preferred, however, that the holes are drilled sometime during the period 20 (FIG. 2) when the ventricle is in the region of maximum contraction. This typically corresponds to a period about 250 to about 400 milliseconds after the R wave. The subsequent expansion of the heart tends to further open the holes and at full diameter resulting in more significant blood flow through the holes. With laser energy delivered in a laser pulse less than 5 milliseconds, preferably in less than 2 milliseconds, more preferably in 1 millisecond or less, the laser pulse has the ability to be placed at anytime during the heart cycle with ease, therefore it need not be synchronized with the heart cycle.

While several particular embodiments of the invention have been illustrated and described, it will be apparent that various modifications can be made without departing from the spirit and scope of, and are encompassed by, the claimed invention and its equivalents.

I CLAIM:

1. A laser system for performing transmyocardial revascularization on a beating heart, comprising:

a laser having a beam operating at a wavelength with very high absorption in myocardial tissue;

means for directing the laser at a wall of the beating heart; and

means for emitting the beam at the wall of the beating heart for about one millisecond to create a revascularizing channel completely through the wall in the about one millisecond.

2. The system of Claim 1 further comprising:

means for sensing a contraction and expansion of the beating heart; and

wherein the emitting means emits the beam during a period of a heart cycle when a ventricle is in a region of maximum contraction.

3. The system of Claim 1 further comprising:

means for sensing a contraction and expansion of the beating heart; and

wherein the emitting means emits the beam during a period from about 250 milliseconds to about 400 milliseconds after a R-wave of a heart cycle.

4. The system of Claim 1 wherein the laser has a beam quality sufficient to focus the beam to the about one millimeter diameter with at least about 20 millimeters of depth of field.

5. The system of Claim 1 wherein the laser produces between about 5 and about 30 joules.

6. The system of Claim 1 wherein the emitting means emits the beam at anytime during a heart cycle.

7. The system of Claim 1 wherein the emitting means emits a

single, one millisecond pulse.

8. A method for myocardial revascularization of a beating heart, comprising:

emitting laser energy with a beam operating at a wavelength with very high absorption in myocardial tissue at a wall of the beating heart; and

creating a revascularizing channel completely through the wall of the beating heart within five milliseconds or less with the beam.

9. The method of Claim 8 wherein the laser energy produces between about 5 to about 30 joules.

10. The method of Claim 8 wherein the laser energy is produced with a carbon dioxide laser operating at the wavelength of 10.6 μm.

11. The method of Claim 8 wherein the creating step is performed at anytime during a heart cycle.

12. The method of Claim 8 wherein the creating step is performed during a period of a heart cycle when a ventricle is in a region of maximum contraction.

13. The method of Claim 8 wherein the creating step is performed during a period from about 250 milliseconds to about 400 milliseconds after a R-wave of a heart cycle.

14. The method of Claim 8 wherein the beam has a one millimeter diameter and at least about 20 millimeters of depth of field.

15. The method of Claim 8 wherein the channel is created within one millisecond.

16. A method for myocardial revascularization of a beating heart, comprising:

emitting a single, one millisecond laser pulse with a beam operating at a wavelength with very high absorption in myocardial tissue at a wall of the beating heart; and

creating a revascularizing channel having about a one millimeter diameter completely through the wall of the beating heart with the single, one millisecond laser pulse.

17. The method of Claim 16 wherein the revascularizing channel has a depth of at least about 20 millimeters.

18. The method of Claim 16 wherein the creating step is performed at anytime during a heart cycle.

19. The method of Claim 16 wherein the creating step is performed during a period of a heart cycle when a ventricle is in a region of maximum contraction.

20. The method of Claim 16 wherein the creating step is performed during a period from about 250 milliseconds to about 400 milliseconds after a R-wave of a heart cycle.

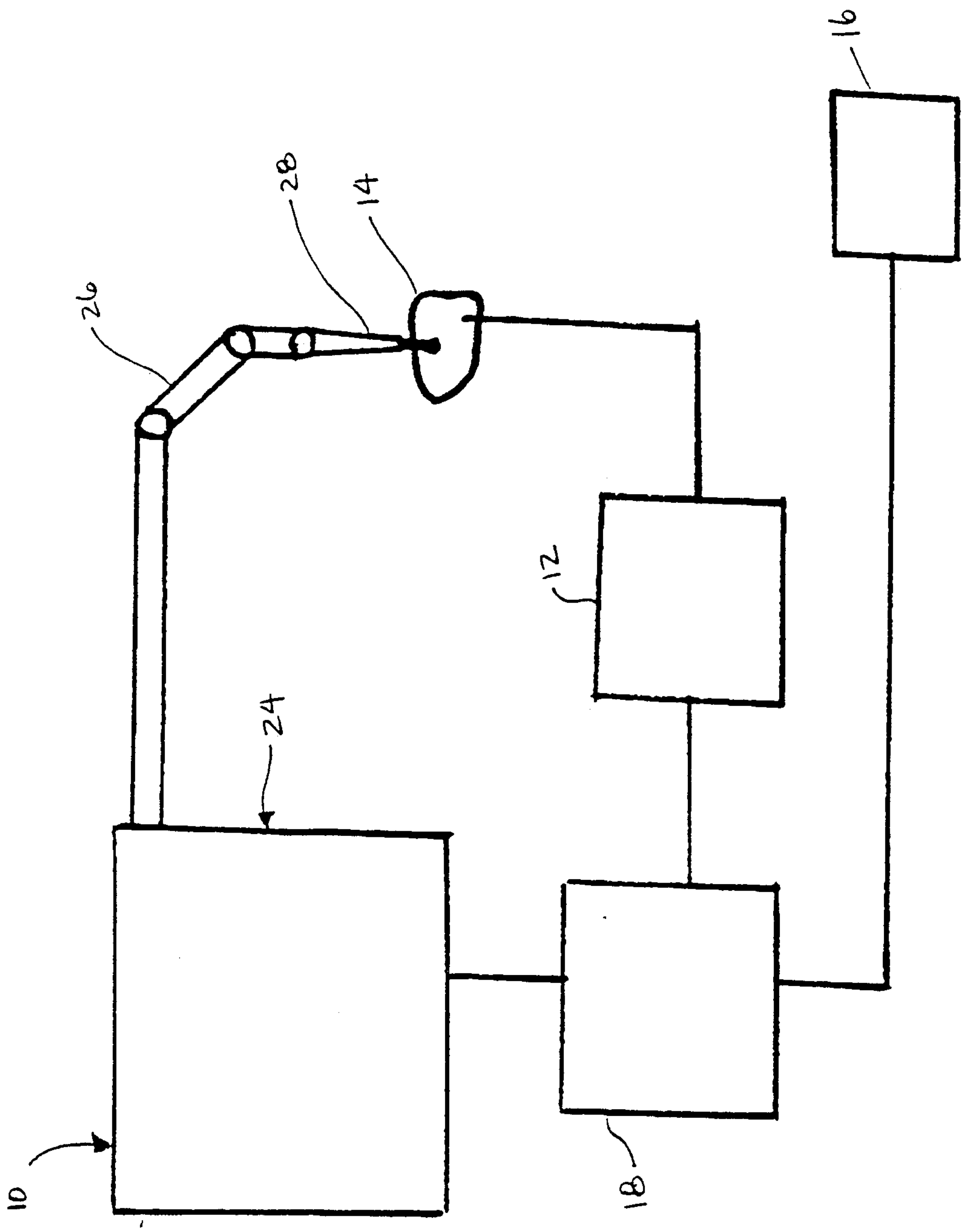

FIG. 1

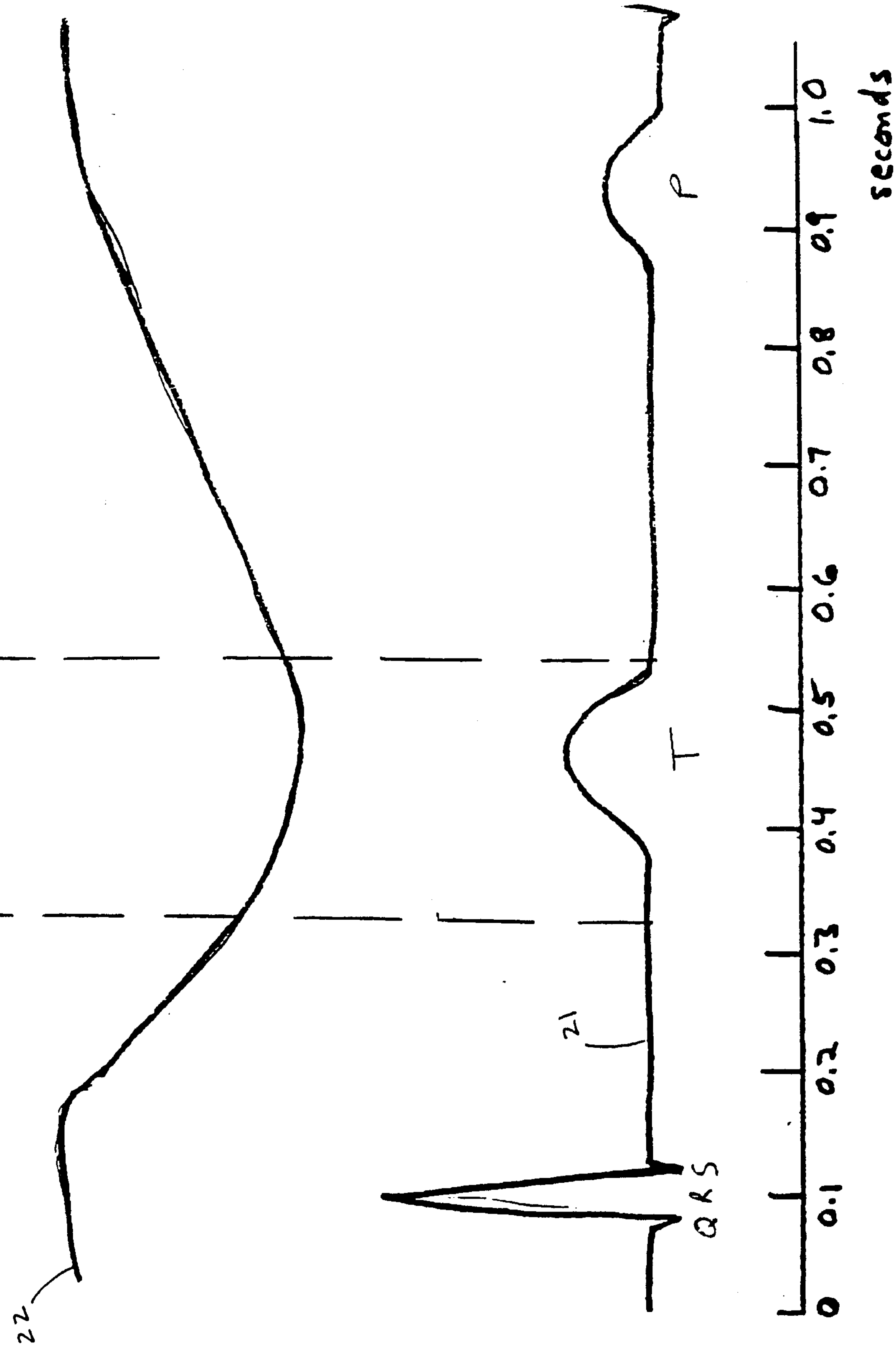

FIG. 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/00220

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61B 5/06; A61N 1/362
US CL :606/12
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. : 604/21, 22; 606/10, 11; 607/9, 24, 25

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,672,170 A (CHO et al) 30 September 1997, entire document.	1-3, 6, 8, 10-13, 16, 18-20 ---------------- 4, 5, 7,9, 14, 15, 17
A	US 5,703,985 A (OWYANG) 30 December 1997.	1-20

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