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NOTICE OF ENTITLEMENT

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The basic application(s) listed on the Declaration under Article 8 of the PCT is/are the first application(s) made in a Convention country in respect of the invention.

DATED this Twenty-Fourth day of November 1995

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John Gordon Hinde

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(71) Applicant(s)
VIDAMED, INC.

(72) Inventor(s)
STUART D EDWARDS; HUGH R SHARKEY; INGEMAR H. LUNDQUIST; RONALD G LAX; BRUNO STRUL

(74) Attorney or Agent
SPRUSON & FERGUSON , GPO Box 3898, SYDNEY NSW 2001

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(57) Claim

1. An apparatus for the treatment of a human male having a bladder with a base with a urethra formed by a urethral wall extending into the base of the bladder and a prostate having tissue surrounding the urethral wall comprising an elongate probe member having proximal and distal extremities and being sized so that it can be introduced into the urethra, said elongate probe member having a passage extending from the proximal extremity to the distal extremity, at least one stylet disposed in the passage extending from the proximal extremity to the distal extremity of the elongate probe member, handle means coupled to the proximal extremity of the elongate probe member, means carried by the handle means and secured to the stylet for advancing the distal extremity of the stylet through the urethral wall and into the tissue of the prostate, a radio frequency power supply for delivering radio frequency energy to the stylet, said radio frequency power supply including means for terminating the application of radio frequency power to the stylet when sufficient radio frequency energy has been delivered to the tissue of the prostate to ablate tissue in the prostate.

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(71) Applicant: VIDAMED, INC. [US/US]; Suite 101, 1380 Willow Road, Menlo Park, CA 94025 (US).

(72) Inventors: EDWARDS, Stuart, D.; 1681 Austin Avenue, Los Altos, CA 94024 (US). SHARKEY, Hugh, R.; 654 Iris Street, Redwood City, CA 94061 (US). LUNDQUIST, Ingemar, H.; 17 Mile Drive At The Dunes, Pebble Beach, CA 93953 (US). LAX, Ronald, G.; 10724 Glenbrook Estates Court, Grass Valley, CA 95945 (US). STRUL, Bruno; 918 Bautista Court, Palo Alto, CA 94303 (US).

(74) Agents: GRUSE, Robert, F. et al.; Oblon, Spivak, McClelland, Maier & Neustadt, 4th Floor, 1755 South Jefferson Davis Highway, Arlington, VA 22202 (US).

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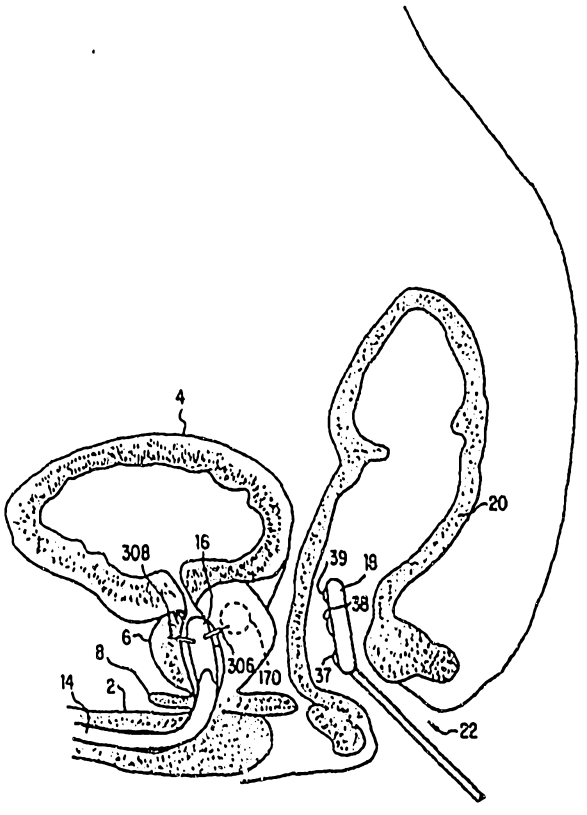
(57) Abstract

A method and an apparatus (14) is disclosed for delivering controlled heat to perform ablation to treat the benign prosthetic hypertrophy or hyperplasia (BPH). According to the method and the apparatus (14), the energy is transferred directly into the tissue mass (6) which is to be treated in such a manner as to provide tissue ablation without damage to surrounding tissues. Automatic shutoff occurs when any one of a number of surrounding areas to include the urethra (2) or surrounding mass or the adjacent organs (6) exeed predetermined safe temperature limits. The constant application of the radio frequency energy over a maintained determined time provides a safe procedure which avoids electro-surgical and other invasive operations while providing fast relief to BPH with a short recovery time. The procedure may be accomplished in a doctor's office without the need for hospitalization or surgery.



Description

BPH Ablation Method and Apparatus

Relationship to Copending Application

This application is a continuation-in-part of copending application serial no. 07/929,638 filed August 12, 1992 and serial no. 08/012,370 filed February 2, 1993, the entire contents of which are hereby incorporated by reference.

Technical Field

This invention is directed to a unique method and device for delivering controlled heat to perform ablation to treat benign prosthetic hypertrophy or hyperplasia (BPH). The method and the apparatus deliver this controlled heat into tissue penetrated by devices such as those disclosed in the copending above-referenced applications.

Background Art

Treatment of cellular tissues usually requires direct contact of target tissue with a medical instrument, usually by surgical procedures exposing both the target and intervening tissue to substantial trauma. Often, precise placement of a treatment probe is difficult because of the location of a target tissue in the body or the proximity of the target tissue to easily damaged, critical body organs, nerves, or other components.

Benign prostatic hypertrophy or hyperplasia (BPH), for example, is one of the most common medical problems experienced by men over 50 years old. Urinary tract obstruction due to prostatic hyperplasia has been recognized since the earliest days of medicine. Hyperplastic enlargement of the prostate gland often leads to compression of the urethra, resulting in obstruction of the urinary tract and the subsequent development of symptoms including frequent urination, decrease in urinary flow, nocturia, pain, discomfort, and dribbling. The association of BPH with aging has been shown to exceed 50%

in men over 50 years of age and increases in incidence to over 75% in men over 80 years of age. Symptoms of urinary obstruction occur most frequently between the ages of 65 and 70 when approximately 65% of men in his age group have prostatic enlargement.

Currently there is no proven effective nonsurgical method of treatment of BPH. In addition, the surgical procedures available are not totally satisfactory. Currently patients offering from the obstructive symptoms of this disease are provided with few options: continue to cope with the symptoms (i.e., conservative management), submit to drug therapy at early stages, or submit to surgical intervention. More than 30,000 patients per year undergo surgery for removal of prostatic tissue in the United States. These represent less than five percent of men exhibiting clinical significant symptoms.

Those suffering from BPH are often elderly men, many with additional health problems which increase the risk of surgical procedures. Surgical procedures for the removal of prostatic tissue are associated with a number of hazards including anesthesia associated morbidity, hemorrhage, coagulopathies, pulmonary emboli and electrolyte imbalances. These procedures performed currently can also lead to cardiac complications, bladder perforation, incontinence, infection, urethral or bladder neck stricture, retention of prostatic chips, retrograde ejaculation, and infertility. Due to the extensive invasive nature of the current treatment options for obstructive uropathy, the majority of patients delay definitive treatment of their condition. This circumstance can lead to serious damage to structures secondary to the obstructive lesion in the prostate (bladder hypertrophy, hydronephrosis, dilation of the kidney pelves, etc.) which is not without significant consequences. In addition, a significant number of patients with symptoms sufficiently severe to warrant surgical intervention are poor operative risks and are poor candidates for prostatectomy. In

addition, younger men suffering from BPH who do not desire to risk complications such as infertility are often forced to avoid surgical intervention. Thus the need, importance and value of improved surgical and non-surgical methods for treating BPH is unquestionable.

High-frequency currents are used in electrocautery procedures for cutting human tissue especially when a bloodless incision is desired or when the operating site is not accessible with a normal scalpel but presents an access for a thin instrument through natural body openings such as the esophagus, intestines or urethra. Examples include the removal of prostatic adenomas, bladder tumors or intestinal polyps. In such cases, the high-frequency current is fed by a surgical probe into the tissue to be cut. The resulting dissipated heat causes boiling and vaporization of the cell fluid at this point, whereupon the cell walls rupture and the tissue is separated.

Destruction of cellular tissues *in situ* has been used in the treatment of many diseases and medical conditions alone or as an adjunct to surgical removal procedures. It is often less traumatic than surgical procedures and may be the only alternative where other procedures are unsafe. Ablative treatment devices have the advantage of using a destructive energy which is rapidly dissipated and reduced to a non-destructive level by conduction and convection forces of circulating fluids and other natural body processes.

Microwave, radiofrequency, acoustical (ultrasound) and high energy (laser) devices, and tissue destructive substances have been used to destroy malignant, benign and other types of cells and tissues from a wide variety of anatomic sites and organs. Tissues treated include isolated carcinoma masses and, more specifically, organs such as the prostate, glandular and stromal nodules characteristic of benign prostate hyperplasia. These devices typically include a catheter or cannula which is used to carry a radiofrequency electrode or microwave

antenna through a duct to the zone of treatment and apply energy diffusely through the duct wall into the surrounding tissue in all directions. Severe trauma is often sustained by the duct wall during this cellular destruction process, and some devices combine cooling systems with microwave antennas to reduce trauma to the ductal wall. For treating the prostate with these devices, for example, heat energy is delivered through the walls of the urethra into the surrounding prostate cells in an effort to kill the tissue constricting the urethra. Light energy, typically from a laser, is delivered to prostate tissue target sites by "burning through" the wall of the urethra. Healthy cells of the duct wall and healthy tissue between the nodules and duct wall are also indiscriminately destroyed in the process and can cause unnecessary loss of some prostate function. Furthermore, the added cooling function of some microwave devices complicates the apparatus and requires that the device be sufficiently large to accommodate this cooling system.

Application of liquids to specific tissues for medical purposes is limited by the ability to obtain delivery without traumatizing intervening tissue and to effect a delivery limited to the specific target tissue. Localized chemotherapy, drug infusions, collagen injections, or injections of agents which are then activated by light, heat or chemicals would be greatly facilitated by a device which could conveniently and precisely place a fluid supply catheter opening at the specific target tissue.

Disclosure of the Invention

It is a principal object of the present invention to provide a method and an apparatus which delivers controlled heat to target tissue through intervening tissues without substantially heating or effecting those intervening tissues. The target tissues are selected for medical action such as tissue destruction. The destruction is limited to precise preselected sites to minimize trauma and

achieve a greater medical benefit.

One of the other principal objects of the invention is to provide a method and an apparatus for precise tissue destruction of body tissues by delivering therapeutic energy directly into the target tissue while minimizing effects on its surrounding tissue.

Another object of the invention is to provide a method of thermal destruction which is automatically controlled so as to shut off when a surrounding environment exceeds a predetermined temperature.

It is another object of the invention to provide a system for delivering power limited over a particular frequency range and limited over a particular power range for a preselected period of time in order to control temperatures in the adjacent tissues to the target tissue and in order to provide parameters of power delivery so that the applied energy does not affect body organs in the vicinity of the prostate and which do not affect any nervous system elements in the vicinity of said prostate.

It is a further object of the present invention to provide a timed application of RF power at a selected voltage and a selected frequency range to be delivered through a catheter. The type of catheter used includes a probe having a stylet guide housing with at least one stylet port in a side wall and a guide means for directing a flexible stylet outward through a stylet port and through intervening tissues at a preselected angle into target tissue.

It is also an object of the present invention to provide a method and a system which monitors the temperature in the environment of the probe end of the catheter by use of thermal sensors attached proximal to the flexible stylets and proximal to the stilette port wherein each of these sensors provide a feedback indicating the display of the temperature. The invention also provides cut-off of RF power when the temperature of any one of the sensors exceeds a respective predetermined maximum value

for each of the sensors is exceeded.

It is also an object of the present invention to provide temperature measurement in adjacent organs of the body of a patient with additional sensors being used to monitor the effect of application of RF power on adjacent portions of the body.

It is a further object of the present invention to provide a voltage delivery system and method which is based upon a calibrated delivery of power which calibration is based upon an impedance typical of a human body.

It is a further obje ct of the present invention to provide for a method of application of a controlled RF power for a predetermined period of time having automatic switch off provisions based upon safety temperature limits within the immediate environment of a catheter delivering the RF voltage and within body organs adjacent to the area of the prostate.

Disclosure of the Invention

According to a first embodiment of this invention, there is provided an apparatus for the treatment of a human male having a bladder with a base with a urethra formed by a urethral wall extending into the base of the bladder and a prostate having tissue surrounding the urethral wall comprising an elongate probe member having proximal and distal extremities and being sized so that it can be introduced into the urethra, said elongate probe member having a passage extending from the proximal extremity to the distal extremity, at least one stylet disposed in the passage extending from the proximal extremity to the distal extremity of the elongate probe member, handle means coupled to the proximal extremity of the elongate probe member, means carried by the handle means and secured to the stylet for advancing the distal extremity of the stylet through the urethral wall and into the tissue of the prostate, a radio frequency power supply for delivering radio frequency energy to the stylet, said radio frequency power supply including means for terminating the application of radio frequency power to the stylet when sufficient radio frequency energy has been delivered to the tissue of the prostate to ablate tissue in the prostate.

According to a second embodiment of this invention, there is provided a method for the treatment of a human male having a bladder with a base with a urethra formed by a urethral wall extending into the base of the bladder and a prostate having tissue surrounding the urethral wall by the use of an elongate probe member having proximal and distal extremities and being sized so that it can be introduced into the urethra, said elongate probe member having a passage extending from the proximal extremity to the distal extremity, at least one stylet disposed in the passage extending from the proximal extremity to the distal extremity of the elongate probe member, handle means coupled to the proximal extremity of the elongate probe member, means carried by the handle means and secured to the stylet for advancing the distal extremity of the stylet through the urethral wall and into the tissue of the prostate, the stylet being comprised of a radio

frequency conductive electrode, an insulating sleeve coaxially disposed on the radio frequency electrode, said handle means including means for advancing and retracting the radio frequency electrode and the insulating sleeve, a radio frequency power supply for delivering radio frequency energy to the radio frequency electrode, said radio frequency power supply including means for terminating the application of radio frequency power to the radio frequency electrode, comprising the steps of delivering radio frequency energy from the radio frequency power supply to the radio frequency electrode and into the tissue of the prostate to cause ablation of tissue in the prostate and terminating the delivery of radio fre y energy to the prostate when an appropriate volume of tissue has been ablated in the prostate by the use of a parameter selected from time, temperature and impedance.

Brief Description of the Drawings

Figure 1 is a cross-sectional drawing of the lower male anatomy showing the placement of a catheter and a prostate probe with the catheter delivering power according to the preferred embodiment of the method of the present invention;

Figure 2 is a top view of a two stylet embodiment of an RF ablation catheter utilising the power application of the present invention;

Figure 2A is a side-view of a non-conductive sleeve covering each stylet of Figure 2.

Figure 3 is a schematic of the power supply for the delivery system of the method of the present invention;

Figure 4 is a view of the front panel of the power delivery system in accordance with the present invention.

Best Mode for Carrying out the Invention

The method of the present invention provides a precise controlled delivery of RF energy to a tissue targeted for

treatment or destruction. The generated power is delivered by means of a catheter providing a stylet which includes a solid or hollow probe adapted to be passed from a catheter port through normal tissue to a target tissue. Typically the stylet is of the type disclosed in copending patent application Serial No. 07/929,638 and 08/012,370. A stylet is shaped in order to facilitate easy passage through the issue and may be composed of a thin wire or rod or can be a thin hollow tube or other shape having a longitudinal lumen for introducing fluids or for removing materials. The stylet is usually and preferably formed with sharpened and reduced resistance when it is pushed through the tissue to the target site. The stylet is designed, according to the present invention, as a radio frequency electrode.

The method of the present invention provides an improved precision and control of medical treatment for destroying cells of medically targeted tissue throughout the body. These cells may be within or external to particular body organs. Most particularly the method and the device for delivering the powers useful for treating benign prostate hyperplasia (BPH) and the device and its use as described in the preferred embodiment are designed specifically with respect to BPH. It will be readily apparent to a person of skill in the art that the device and the method can be used to destroy body tissue and any other body cavity or tissue locations that are accessible by percutaneous or endoscopic catheters and is not limited to the prostate. Applications of the device and the method in all of these organs and tissues are intended to be included within the scope of this invention.

BPH is a condition which arises from the benign replication and growth of cells in the prostate, forming glandular and stromal nodules which expand the prostate and constrict the opening of the prosthetic urethra. Glandular modules are primarily concentration within the transition zone, and stromal nodules within the periurethral region. Traditional treatments of this condition have included

surgical removal of the entire prostate gland, digital removal of the adenoma, as well as transurethral resection of the urethral canal and prostate to remove tissue and widen the passage way. One significant serious complication associated with the latter method is iatrogenic sterility. More recently, laser treatments have been applied to remove tissue, limiting bleeding and loss of body fluids. Balloons have also been expanded within the urethra to enlarge its diameter, with and without heat, but have been found to have significant limitations.

Microwave therapy has been provided with some success by positioning a microwave antenna within the prosthetic urethra and generating heat in the tissues surrounding the urethra with a microwave field. Coolants are sometimes applied within the catheter shaft to reduce the temperature of the urethral wall. This necessitates complicated mechanisms to provide cooling of the immediately adjacent tissues while at the same time generating heat in the more distant prosthetic tissue. This technique is similar to microwave hyperthermia. Similarly, radio frequency tissue destruction with electrodes positioned within the urethra has a limited applicability since it necessarily exposes the urethral wall to destructive temperatures. To avoid this, low temperature setting is required to protect the urethra and must be so low that the treatment time required to produce any useful effect is unduly extended, e.g., up to three hours of energy application.

In a preferred embodiment of the present invention, the urethra is used to access the prostate and position RF stylets directly into the tissues or nodules to be destroyed. The portion of the stylet conductor extending from the urethra to the target tissue is enclosed within a longitudinally adjustable sleeve which prevents exposure of the tissue adjacent to the sleeve to the RF current. Therefore, the ablative destruction is confined to the tissue targeted for destruction, namely those causing constriction. More particularly, according to the present

invention the method of delivering power to the electrode stylets is controlled within a power range and frequency range and is limited by a series of temperature sensors positions proximal to the stylets in order to ensure complete protection of surrounding tissues. This is made possible by an automatic cut-off of RF energy to the system upon the sensing of any one of the sensors exceeding a predetermined safe temperature for the region being treated. The method also features automatic power cut-off using additional sensors placed proximal to body organs adjacent to the tissue being treated in order to avoid damage to those adjacent body organs due to increased organ temperature.

Figure 1 is the schematic cross-sectional drawing of the lower male anatomy during the use of a typical device for applying the controlled energy to the treated tissue generated and delivered according to the method and apparatus of the present invention. The urethra 2 extends from the urinary bladder 4 through the prostate 6 and a urogenital diaphragm 8. BPH is a condition characterized by constriction of the portion of the prosthetic urethra caused primarily by proliferation of benign glandular and stroma cells in the prostate. These nodules press the wall of the urethra inwardly restricting the urethral diameter, and may at times press normal tissue outwardly possibly enlarging the prostate. Traditional treatment, short of removal of the prostate, have included either removal of tissue from the urethra to enlarge its lumen by resection or laser tissue destruction, or by expansion and heating of the tissues surrounding the urethra and to a temperature which causes cell damage. The latter method is intended to reduce the swelling or enlargement of the prostate, and restore the urinary passage to at least a portion of its former diameter.

A catheter 14 with a stylet guide 16 is passed downwardly through the urethra into the prostate. The position of the guide 16 is precisely controlled, using an

ultrasound image, for example, obtained from signals received from the conventional ultrasonic transducer 18 inserted into the rectum 20 adjacent to the prostate through the anal opening 22. The guide facilitates easy positioning of the stylet 17 into a precise location under ultrasonic imaging. The guide 18 may also contain sensors 37, 38 and 39 for sensing, within the bowel region, any effects from heating tissue as will be described later. Optionally, the sensors 37, 38 and 39 can be a part of a separate instrument placed into the rectal area after removal of an ultrasonic probe and after the catheter 14 and stylet guide 16 have been positioned. The Figure 1 illustrates too stylets 306 and 308 with the stylet 306 having its end penetrated into the tissue area 170 which represents tissue to be ablated.

Figure 2 is a top view of a two stylet embodiment of an ablation catheter of Figure 1 used to deliver power from the preferred method and apparatus of the present invention. The flexible catheter 300, attached to handle 302, has a terminal stylet guide 304 with two stylets 306 and 308. The handle has stylet sleeve cap 356 and electrode cap 354. The handle is also connected to a RF power connector 303 to be discussed in detail hereinafter. Also shown is a connection for a thermoconnector 307. The portions of the catheter 300 leading from the handle 302 to the stylet guide 304 can optionally have a graduated stiffness. For example, the catheter can be designed to be more stiff near the handle and more flexible near the tip or any other stiffness profile desired. The catheter can be constructed of an inner slotted stainless steel tube with an outer flexible sleeve such as is described in copending application Serial No. 790,648 filed August 11, 1991, the entire contents of which are incorporated herein by reference. It can also be made of a coiled or braided wire to which an outer sleeve is bonded. The stylet of Figure 2 is described in the copending application Serial No. 08/012,370 filed February 2, 1993.

The power delivery method of the present invention is enabled by the power supply delivery system shown in the schematic of Figure 3.

The block labelled 210 illustrates connections to the patient with the inserted stylet guide 16 and the transducer probe 18 having the sensors 37, 38 and 39 in a manner similar to the Figure 1. The stylet guide 16 has two stylets with the illustrated sensors 241 and 243 being respectively attached in the vicinity of the stylet. More particularly, in a preferred embodiment, the stylets 306, 308 of Figure 2 each include a non-conductive sleeve as illustrated in Figure 2A. This non-conductive sleeve is discussed in detailed in copending application Serial No. 08/012,370. For purposes of the present application, the non-conductive sleeve has a tapered leading tip 262 and a rigid proximal portion 264. The center portion or the inner lumen 274 of the non-conductive sleeve 202 receives the stylet 306, 308. A temperature sensor 241 is mounted on the tip. The mounting 243 shown schematically in Figure 3 corresponds to the other of the stylets and would be identical to the placement of the sensor 241. The third illustrated sensor in the stylet guide is labelled 242 and corresponds to a placement inside the guide near the surface. The stylet guide is illustrated with the three sensors 241-243 which send temperature signals through the isolation device 231-233, respectively, in order to provide a temperature measurement at 221, 222, and 223, respectively.

The heating of the stylets 306 and 308 is accomplished through the generation of RF power by means of the crystal oscillator 102 and the transformer circuitry 104 schematically shown in Figure 3. The crystal oscillator in a preferred embodiment delivers effectively a 482KHz rf power to the stylet guide and more particularly to the stylets 306 and 308, respectively. The transformer circuitry is calibrated for an impedance of 100 ohms. The impedance is based upon a median impedance expected in

human patient measurements typical with placements of stylets in the urethra. In the actual operation of the circuitry of figure 3, the impedance varies from the calibrated resistance and this is measured by circuit 204. Because the delivery of the rf energy is monopolar, each patient must have an indifferent electrode 206 to complete the circuit. Typically, these electrodes are large patches which are placed on patient's back and are held by adhesive.

In a preferred arrangement, the transformer circuitry is capable of 16 watts although the normal range of application for purposes of the isolated tissue ablation encountered in BPH is between 5 and 7 watts which is typically applied for three minutes.

The limits on the operation of the circuitry, aside from operator settings and frequency and power maximums, are determined by sensors 241, 242 and 243 associated with the stylet guide 16 and sensors 37, 38 and 39 associated with the rectal probe 16. The processing of the outputs from the sensors 241, 242, 243 and 37, 38 and 39 are identical as shown by the isolation devices 231 to 236 and the temperature measurements 221-226, respectively. The isolation device 231-236 involves a 1500 voltage isolation circuit which in a preferred embodiment is a Burr-Brown isolation device ISO 122JP. The output from this isolation device 231-236 is fed through cold junction compensators 271-276 to the temperature measurement 221-226 circuits and to temperature cut-off circuits 211-216. Each of the isolation devices 231-236 are identical as are the temperature measurement devices 221-226. Each cold junction compensation structure 271-276 provides absolute temperature measurement readings in degree Celsius. Although the circuitry is the same for each of the temperature cut-off circuits 211-216, each of these cut-off circuits have a different temperature limit or may have a different limit. Based upon physiological evaluation to insure against excess overheating in the environment of the

tissue being destroyed and in adjacent organs, the following limits have been set to provide protection to the patient. The sensor cut-off for circuits 211 and 212 correspond to the sensors 241 and 243 and have a setting of 90°C as a cut-off. To illustrate, a temperature of 60°C is sufficient to provide for tissue protein dephasing which provides for the destruction of the tissue. The temperature in the guide 16, as detected by sensor 242 is set by the cut-off circuit 213 and a temperature of 45°C. This insures that no damage occurs to the urethra in which the guide is placed. In other words, the material inside the urethra will not be destroyed if the temperature is maintained at 45° or less. It must be noted that if any one of the cut-off circuits operate, then the entire system is automatically shut-off regardless of any operator decisions. Thus, if either the sensors 241 or 243 reach 90°C or if sensor 242 reaches 45° the device will shut off.

The purpose, as discussed previously, of the sensors 37, 38 and 39, which are typically located in a rectal probe 16, is to prevent adjacent organ damage and particularly to protect against overheating of the bowel. This temperature setting in a preferred embodiment is set at 40°C for each of the sensors 37, 38 and 39. Forty degrees C is a temperature which is only slightly above normal body temperature (37.5°C). Thus, once again, any of the sensors 37, 38 and 39 exceed their predetermined cut-off limit, the entire operation of delivery of the power to the stylets 306, 308 is shut down.

Also shown at Figure 3 is a repetition rate adjuster 245 which can be used to provide a pulsed output delivery of energy to allow for variation in time of delivery of energy based upon physiologic considerations. The pulse output delivery of energy allows for electronic pulsing to provide the ability to adjust intervals between applications of energy in order to provide bursts of energy which, when applied for a short time, does not cause any of the temperature sensors to exceed their predetermined value

but which delivers sufficient energy to kill cells in the in the tissue volume selected for a lesion in the vicinity of the stylet. After the application of such a spike of energy, an interval before the next spike allows a total energy application to be of such a value as to not affect adjacent tissue areas or adjacent organs. In other words, the application of electronic pulsing provides an opportunity for applying an energy spike to have a localized destructive effect in a short period of time while at the same time restricting an overall total energy during a predetermined period so as to not significantly affect tissue masses beyond the desired lesion volume and other body organs. The spike will be applied for a controlled short period of time and have a controlled maximum level so that in an overall cycle of, for example three minutes, the total energy would either be the same as or less than the energy applied during a continuous application which energy is calculated not to trigger any of the temperature sensor cut-off switches.

The electronic pulsing provides an opportunity, when necessary and when desired, to more efficiently destroy cells in a very localized targeted area and still maintain the safety of the method and the apparatus. The temperature limits of the sensor are not exceeded because, as indicated above, the total energy applied is not greater than that which would be applied in a continuous operation.

The monitoring of the application of the electronic pulsing can be accomplished manually based on observed temperatures on the monitor. That is, an operator could observe the approach of a temperature to the cut-off limit and stop the application of energy until a cooling off occurs and then reapply the pulsing energy. Alternatively, such monitoring could be performed electronically based on preset parameters controlled by the necessary spiking of energy required to destroy a certain cell area and the subsequent electronic monitoring of temperature increase and temperature decrease rates. None of these electronic

pulsing steps either accomplished manually or electronically based upon physiological considerations would affect the safety of the patient because each of the temperature cut-off switches would still function to automatically shut down the entire power supply if any one of those temperature sensors either in adjacent mass tissue of the stylets or the sensor in the catheter guide in the urethra or any adjacent body organ would exceed its preset safety temperature. Electronic pulsing either accomplished manually or through an electronic physiological scheme provides an opportunity through the pulse repetition rate adjustor 245 to maximize the efficiency of the destruction of the target mass tissue without adversely affecting the surrounding tissue or adjacent body organs.

The operation of the power delivery system in accordance with the method of the present invention will now be discussed in conjunction with Figures 3 and 4 with Figure 4 representing the front panel of a preferred embodiment of the operating system. The relationship between Figures 3 and 4 is such that the outputs from the various measurements in Figure 3 labeled A-I refer to the displays A-I in the front panel of the power supply of Figure 4. Display A shows the power which is set by an operator to be delivered by the supply and the transformer circuitry 104 in particular. There is another power display B which is a display of the actual delivered power. As discussed previously, the power supply was calibrated for an impedance load of 100 ohms. Any variance between the impedance of 100 ohms and a particular patient will bring about slight variations between the power which is set in the display A and that which actually delivered and measured by circuitry 203 and displayed at B. In order to detect circuit completion, impedance measure 204 applies a display of the impedance to the display panel C on the front of the device. The remaining displays D-I associated

with the temperature measuring devices 221-226 provide a display on the front panel of the temperature of each of the sensors 241-243 from the stylet guide 16 and the sensors 37-39 from the probe 18. Appropriate labeling on the front panel of Figure 4 readily identifies which of the sensors is being monitored. It must be emphasized that the monitoring by the operator of the temperature is completely independent of the operation of the cut-off circuitry 211-216 which, as has been previously indicated, operates to automatically shut off the system regardless of any action taken by the operator. No further operation or restarting will occur until the temperatures of sensors decrease below their cut-off limit values.

In a preferred embodiment, connectors 47 and 48 provide for attachment to the various probes with one of the connections 47 providing an output to deliver power to the stylet as well as provide a sensor connection to receive temperature signals from the three sensors 241, 242 and 243. Separate connector 48 receives the temperature delivered from sensors 37, 38 and 39.

Although there have been illustrated three sensors associated with the stylet guide and three sensors associated with the rectal probe 18, it can be readily seen that additional sensors or differently placed sensors may be used with temperature cut-off limits being set in recognition of the physiological implications resulting from temperatures at other parts of the body.

Also in accordance with a preferred embodiment, the sensors 37-39 and 241-243 are thermocouples although other forms of temperature sensors may be contemplated.

The RF energy frequency delivered by the preferred embodiment of the Figures 3 and 4 has, as mentioned previously, a frequency of 482 KHz. Other frequencies are available with the range being determined by frequencies which do not substantially effect any physiological change

within the body particularly as regard to the nervous system or any sensitive organs in the current path. Using those considerations, the frequency range extends from above approximately 250 KHz in order to avoid damage based solely on the frequency of the signal. Other damage to be avoided of course results from the application of high voltages and large power. Particularly, what must be avoided are large power surges which can cause severe damage. Such large power surges can readily occur in electrosurgery when a particular impedance is being significantly altered as a result of tissue destruction. Such rapid changes in impedance cause extremely high voltages to occur which can severely damage adjacent nervous system elements and neighboring organ functionings resulting in unacceptable rates of impotency.

The present method of power delivery avoids this drastic change in impedance levels and particularly avoids surges of electricity based upon the continuous delivery of constant energy with no significant variation in the impedance of the circuitry.

In the alternate embodiment provided by the operation of the previously discussed pulsing by repetition adjustment, the total energy over any significant period of time remains substantially constant and the impedance level remains constant in sharp contrast to electrosurgery which has tremendously high energy peaks caused by breakdown in impedance which often occurs during the electrosurgery operation without any reliable feedback control.

Tissue ablation in the desired area of treatment, in accordance with the embodiments of the present invention, results from the precise application by way of the stylets of low power substantially constant energy delivery resulting in minimal effect on the adjoining healthy tissue and on neighboring nervous system elements and body organs.

For purposes of treating DPH the method of treatment

using the power delivery system of the Figures 3 and 4 involves the operator applying an energy level of between 5 and 7 watts for 3 minutes, followed by repositioning of the stylet or stylets to other areas of treatment and the subsequent reapplication for an additional 3 minutes of the same range of energy. The number of applications is determined by the extent and the location of the tissue to be ablated. During each operation, temperature cut-off limitation circuitry affords the necessary protection due to any unexpected rise in temperature and the temperature limitations assure control of the environment immediately adjacent the tissues being treated as well as the urethra and any adjacent organs. The protection of the adjacent organs with respect to temperature rise is provided by the temperature cut-off limits associated with sensors 37, 38 and 39.

Obviously, numerous additional variations and modifications of the present invention are possible in light of the above teachings. It is therefore to be understood that, within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

The claims defining the invention are as follows:

1. An apparatus for the treatment of a human male having a bladder with a base with a urethra formed by a urethral wall extending into the base of the bladder and a prostate having tissue surrounding the urethral wall comprising an elongate probe member having proximal and distal extremities and being sized so that it can be introduced into the urethra, said elongate probe member having a passage extending from the proximal extremity to the distal extremity, at least one stylet disposed in the passage extending from the proximal extremity to the distal extremity of the elongate probe member, handle means coupled to the proximal extremity of the elongate probe member, means carried by the handle means and secured to the stylet for advancing the distal extremity of the stylet through the urethral wall and into the tissue of the prostate, a radio frequency power supply for delivering radio frequency energy to the stylet, said radio frequency power supply including means for terminating the application of radio frequency power to the stylet when sufficient radio frequency energy has been delivered to the tissue of the prostate to ablate tissue in the prostate.

2. Apparatus as in Claim 1 wherein the radio frequency power supply is capable of delivering up to 16 watts of radio frequency power.

3. Apparatus as in Claim 2 wherein said radio frequency power is delivered for a period of at least three minutes at a power ranging from 5-7 watts.

4. Apparatus as in Claim 1 wherein the stylet is comprised of a radio frequency conductive electrode, an insulating sleeve coaxially disposed on the radio frequency electrode.

5. Apparatus as in Claim 4 wherein the insulating sleeve has a distal extremity, first temperature sensing means carried by the insulating sleeve in the distal extremity thereof, the power supply means including means for terminating the delivery of radio frequency power to the radio frequency electrode when the temperature measured by the temperature sensing means exceeds 90°C.

6. Apparatus as in Claim 5 further comprising a second temperature sensing means carried by the elongate probe member and disposed proximal of the first temperature sensing means, the radio frequency power supply means including means for terminating the application of radio frequency power to the radio frequency electrode when the temperature at the second temperature sensing means exceeds 45°.

7. Apparatus as in Claim 1 wherein the radio frequency power supply includes means for terminating the application of power based upon at least one parameter selected from temperature, time and impedance.

8. Apparatus as in Claim 7 wherein the human being has a rectum further and wherein the temperature parameter is provided by a temperature sensor disposed in the rectum.

9. Apparatus as in Claim 7 further comprising first and second temperature sensors carried by the elongate probe member with the first temperature sensor being

disposed on one side of the urethral wall and in the tissue of the prostate and the second temperature sensor being disposed on the other side of the urethral wall, the temperature parameter being provided by either of said first and second temperature sensors.

10. Apparatus as in Claim 1 wherein said radio frequency power supply includes means for delivering radio frequency power at substantially constant incremental and decremental power levels.

11. A method for the treatment of a human male having a bladder with a base with a urethra formed by a urethral wall extending into the base of the bladder and a prostate having tissue surrounding the urethral wall by the use of an elongate probe member having proximal and distal extremities and being sized so that it can be introduced into the urethra, said elongate probe member having a passage extending from the proximal extremity to the distal extremity, at least one stylet disposed in the passage extending from the proximal extremity to the distal extremity of the elongate probe member, handle means coupled to the proximal extremity of the elongate probe member, means carried by the handle means and secured to the stylet for advancing the distal extremity of the stylet through the urethral wall and into the tissue of the prostate, the stylet being comprised of a radio frequency conductive electrode, an insulating sleeve coaxially disposed on the radio frequency electrode, said handle means including means for advancing and retracting the radio frequency electrode and the insulating sleeve, a radio frequency power supply for delivering radio frequency energy to the radio frequency electrode, said radio frequency power supply including means for terminating the application of radio frequency power to the radio frequency electrode, comprising the steps of delivering radio frequency energy from the radio frequency power supply to the radio frequency electrode and into the tissue of the prostate to cause ablation of tissue in the prostate and terminating the delivery of radio frequency energy to the prostate when an appropriate volume of tissue has been ablated in the prostate by the use of a parameter selected from time, temperature and impedance.

12. A method as in Claim 11 wherein said radio frequency energy is delivered for a period of at least three minutes at a power ranging from 5-7 watts.

13. An apparatus for the treatment of benign prosthetic hypertrophy or hyperplasia, set apparatus, substantially as hereinbefore described with reference to the accompanying drawings.

Dated 19 May, 1997
Vidamed, Inc.

Patent Attorneys for the Applicant/Nominated Person
SPRUSON & FERGUSON

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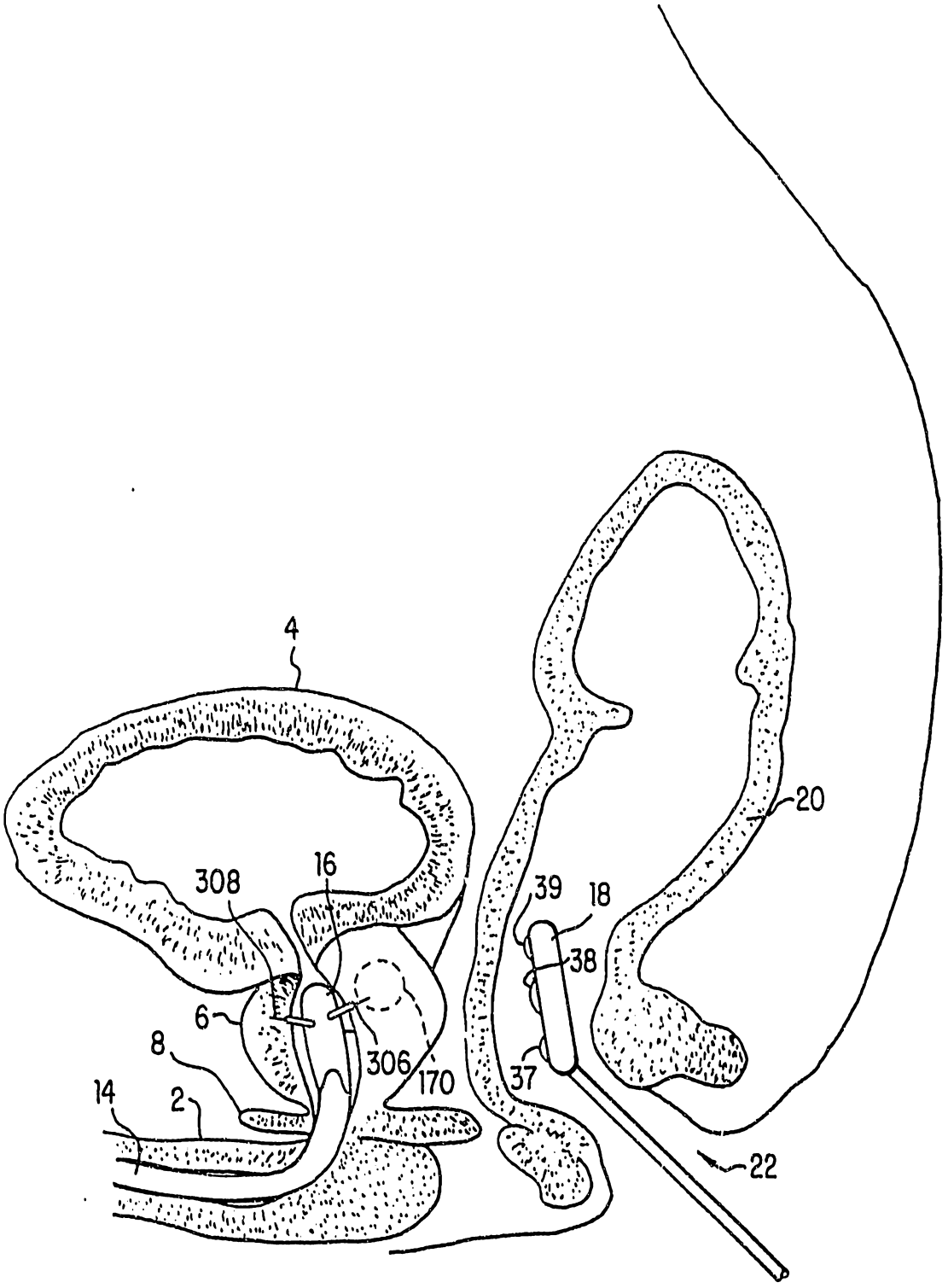


FIG. 1

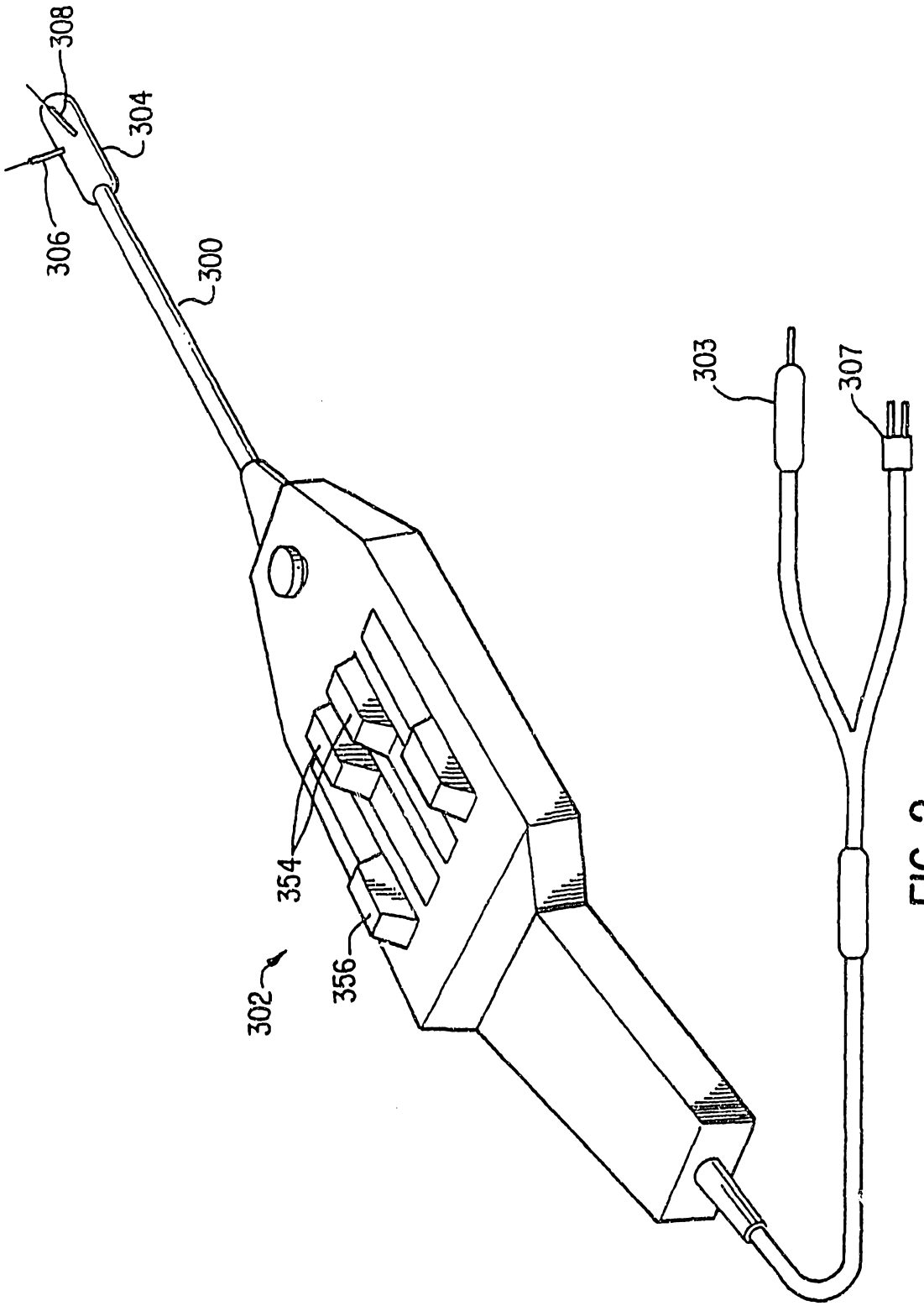


FIG. 2

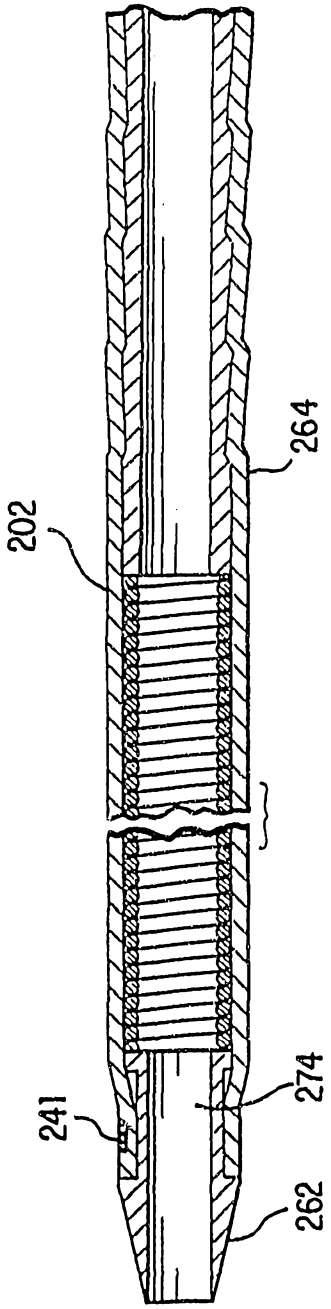


FIG. 2A

FIG. 3A

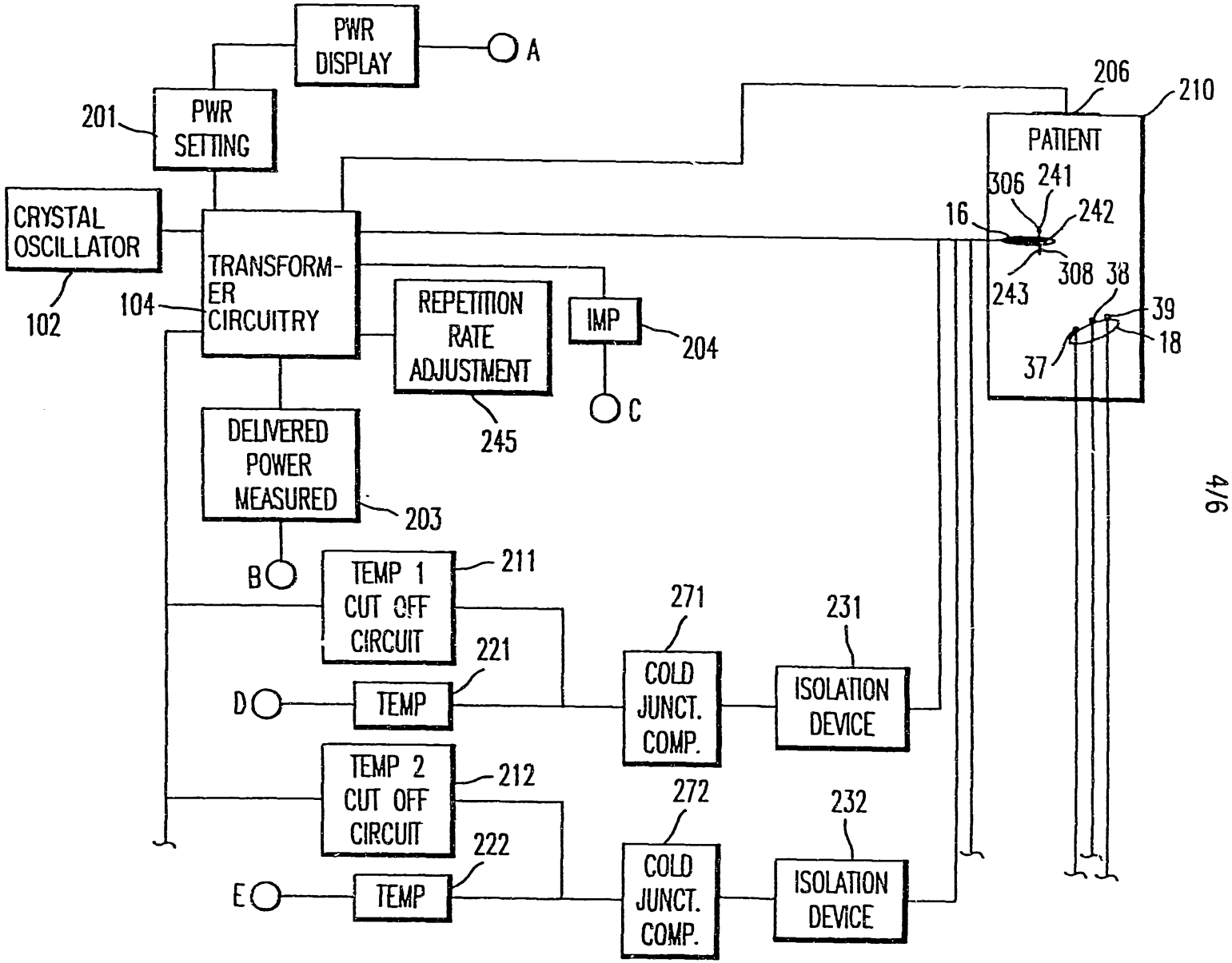
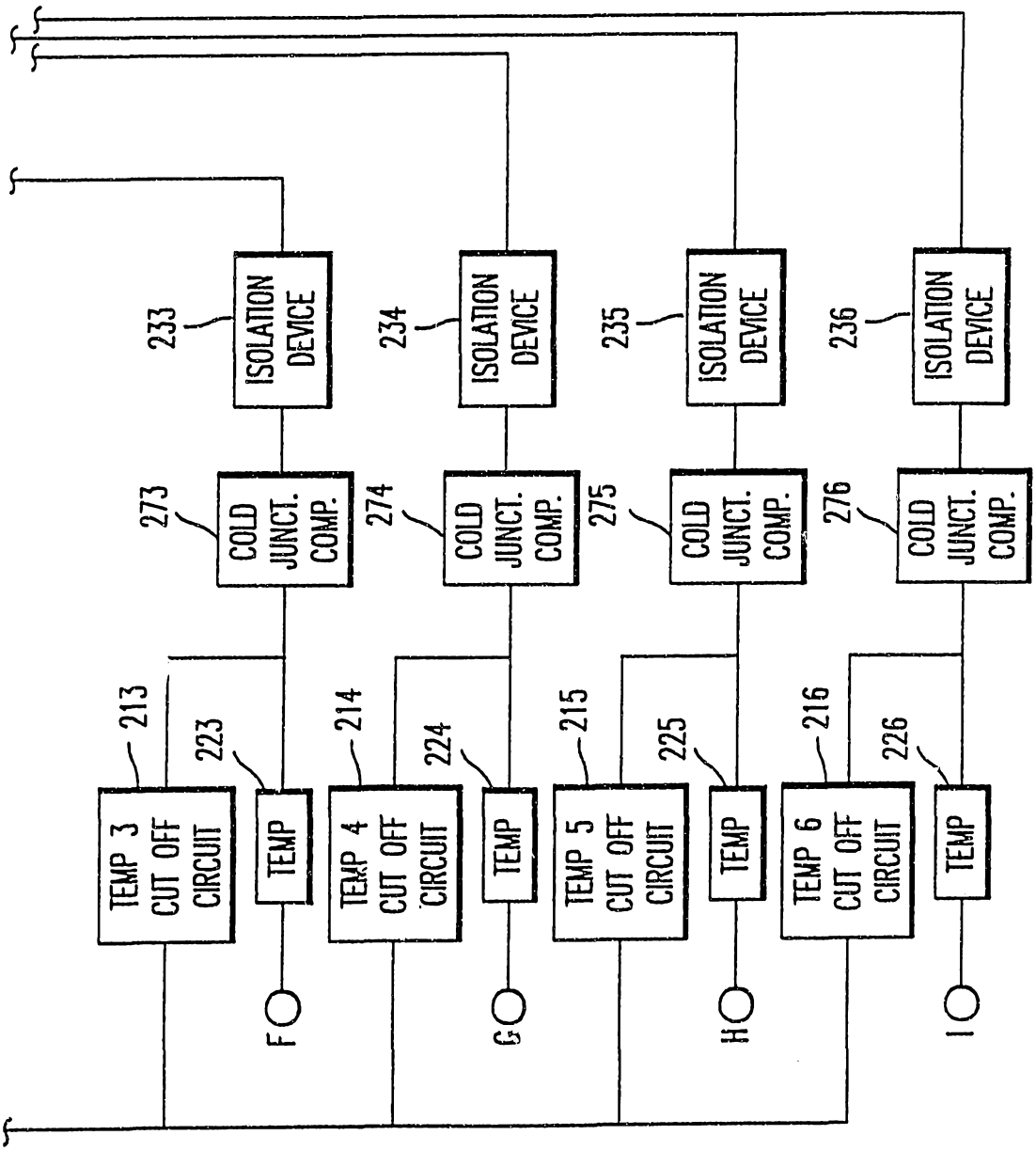

PWR DISPLAY
A
201
PWR SETTING
206
210
PATIENT
306
241
242
16
243
308
38
39
18
37
CRYSTAL OSCILLATOR
102
104
TRANSFORM-ER CIRCUITRY
REPETITION RATE ADJUSTMENT
245
IMP
204
C
DELIVERED POWER MEASURED
203
B
TEMP 1 CUT OFF CIRCUIT
211
271
231
221
D
TEMP
COLD JUNCT. COMP.
ISOLATION DEVICE
TEMP 2 CUT OFF CIRCUIT
212
272
232
222
E
TEMP
COLD JUNCT. COMP.
ISOLATION DEVICE

FIG. 3B


233
ISOLATION DEVICE
234
ISOLATION DEVICE
235
ISOLATION DEVICE
236
ISOLATION DEVICE
273
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274
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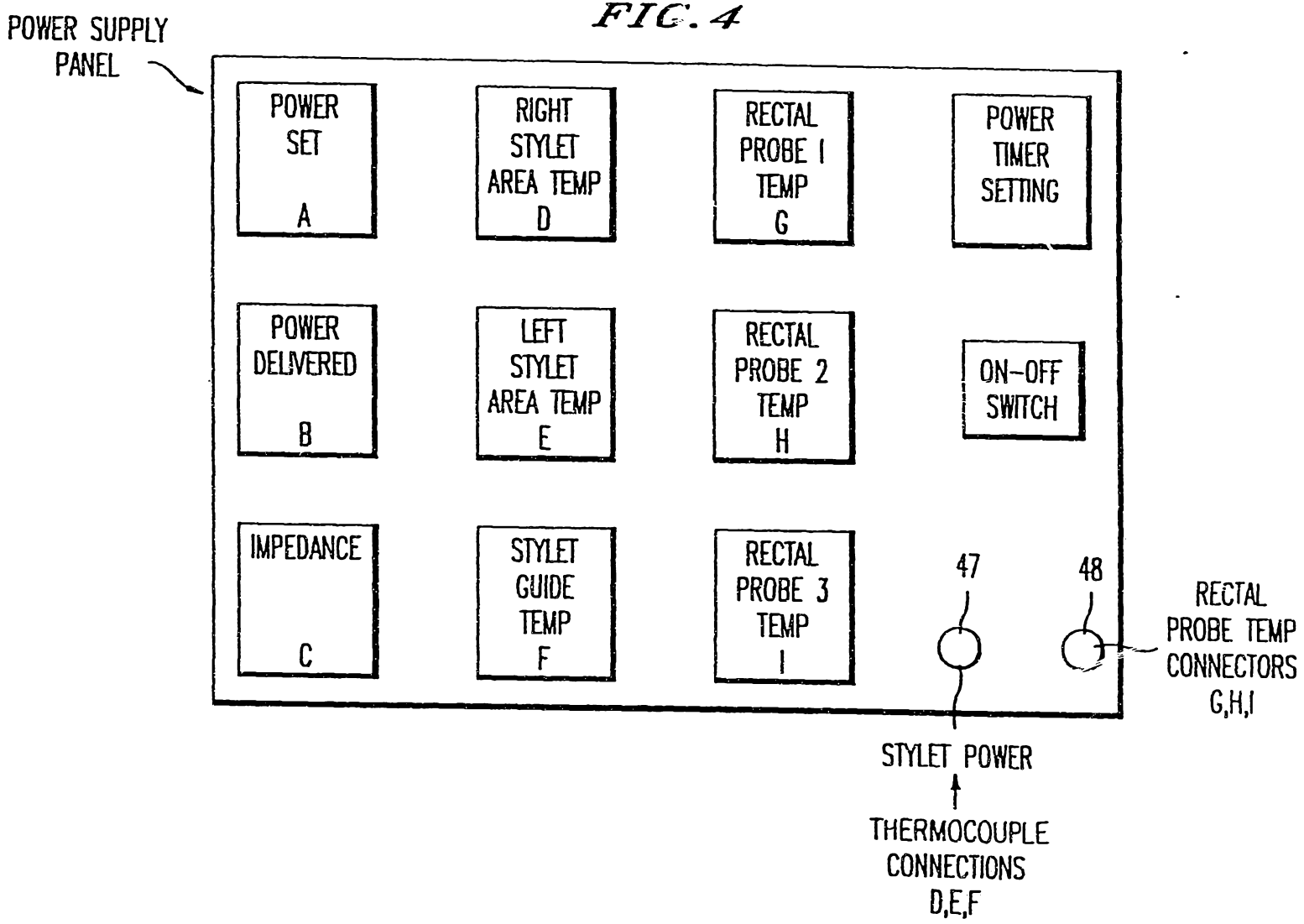
275
COLD JUNCT. COMP.
276
COLD JUNCT. COMP.
213
TEMP 3 CUT OFF CIRCUIT
223
TEMP
214
TEMP 4 CUT OFF CIRCUIT
224
TEMP
215
TEMP 5 CUT OFF CIRCUIT
225
TEMP
216
TEMP 6 CUT OFF CIRCUIT
226
TEMP
F
G
H
I

FIG. 4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POWER SET A
RIGHT STYLET AREA TEMP D
RECTAL PROBE 1 TEMP G
POWER TIMER SETTING
POWER DELIVERED B
LEFT STYLET AREA TEMP E
RECTAL PROBE 2 TEMP H
ON-OFF SWITCH
IMPEDANCE C
STYLET GUIDE TEMP F
RECTAL PROBE 3 TEMP I
47
48
RECTAL PROBE TEMP CONNECTORS G,H,I
STYLET POWER
THERMOCOUPLE CONNECTIONS D,E,F

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/05141

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 17/20
US CL :604/22

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. : 128/24AA; 604/19-22, 53, 164, 280; 606/39, 45, 607/96, 98-102, 112, 115, 116, 138, 156

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

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,565,200, (COSMAN), 21 January 1986. See Fig. 3.	1-23
X --- Y	US, A, 4,311,154, (STERZER ET AL.), 19 January 1982. See column 6 lines 21-37, and elements (80), (102), (104), (106) and (110)	1-12, 14-17, 20 ---------- 1-23
X --- P Y	US, A, 5,249,585, (TURNER ET AL.), 05 October 1993. See elements (14), (16), (18) and (20).	1-12, 14, 16 ---------- 1-23
Y	US, A, 5,122,137, (LENNOX), 16 June 1992. This patent teaches an RF modulating power source and thermocouple sensors. See entire document.	18-23

☐ 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 of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"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)	"&"	document member of the same patent family
"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 the actual completion of the international search 04 AUGUST 1994	Date of mailing of the international search report 23 SEP 1994
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer CHALIN SMITH Telephone No. (703) 308-2988

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