

TITLE

5 Ablation apparatus and system to limit nerve conduction

FIELD OF INVENTION

10 The present invention relates to a method and device used in the field of Minimally Invasive Surgery (or MIS) for interrupting the flow of signals through nerves. These nerves may be rendered incapable of transmitting signals either on a temporarily (hours, days or weeks) or a permanent (months or years) basis. This new device itself consists of a single puncture system, which incorporates both an active and return electrode capable
15 of creating areas of nerve destruction, inhibition and ablation; a generator for precisely delivering RF energy, and the method necessary for properly locating the active tip and generating energy to ablate target nerves.

20

BACKGROUND OF THE INVENTION

The human nervous system is used to send and receive signals. The pathway taken by the nerve signals convey sensory information such as pain, heat, cold and touch and
25 command signals which cause movement (e.g. muscle contractions).

Often extraneous, undesired, or abnormal signals are generated (or are transmitted). Examples include (but are not limited to) the pinching of a minor nerve in the back,

which causes extreme back pain, or the compression (or otherwise activation) of nerves causing referred pain. Also with certain diseases the lining of the nerves is compromised, or signals are spontaneously generated, which can cause a variety of maladies, from seizures to pain or (in extreme conditions) even death. Abnormal signal activations can
5 cause many other problems including (but not limited to) twitching, tics, seizures, distortions, cramps, disabilities (in addition to pain), other undesirable conditions, or other painful, abnormal, undesirable, socially or physically detrimental afflictions.

This device can be used to treat various types of nerve conditions. Such as functional applications to innervations of the posterior neck muscles that will relieve
10 headaches, muscle strain, and pain. The device can be used to treat abnormal muscle activity a result of over stimulation of peripheral nerves, for relief of pain, spasticity, and dystonias. Further, conditions such as hyperhidrosis, rhinorrhea, drooling, and facial flushing, caused by the overactive signals from sympathetic and parasympathetic nerve path ways, can be treated.

15 In other situations, the normal conduction of nerve signals can cause undesirable effects. For example, in cosmetic applications the activation of the corrugator supercilli muscle causes frown lines which may result in permanent distortion of the brow (or forehead); giving the appearance of premature aging. By interruption of the corrugator supercilli activation nerves, this phenomenon may be terminated. Other cosmetic
20 applications include all neck and facial expression muscles, which are innervated by cranial nerves (including, but not limited to, the orbicularis oculi, orbicularis ori, frontalis, procerus, temporalis, masseter, zygomaticus major, depressor anguli oris, depressor labii inferioris, mentalis, platysma, and/or corrugator supercili muscles). Further, Platysma myoides, Procerus muscles, back muscles, back pain, and other
25 pain/abnormal muscle or nerve activations would be treatable.

This technology describes an improved method of interrupting signal flows through nerve fibers with a new single puncture technique; used in the emerging field of Minimally Invasive Surgery (or MIS). Interrupting such flows is done using electricity to form an electrical circuit with the nerve. The circuit created is formed with a source

of energy connected to an active electrode with a return path again connected to the source.

Traditional electrosurgical procedures use either a unipolar or bipolar device connected to that energy source. A unipolar electrode system includes a small surface
5 area electrode, and a return electrode. The return electrode is generally larger in size, and is either resistively or capacitively coupled to the body. Since the same amount of current must flow through each electrode to complete the circuit, the heat generated in the return electrode is dissipated over a larger surface area, and whenever possible, the return
10 electrode is located in areas of high blood flow (such as the biceps, buttocks or other muscular or highly vascularized area) so that heat generated is rapidly carried away, thus preventing a heat rise and consequent burns of the tissue. The advantage of these system is the ability to place the unipolar probe exactly where it is needed and optimally focus the energy where desired. The disadvantage of the system is that the return electrode must be properly placed and in contact throughout the procedure. A resistive return
15 electrode would typically be coated with a conductive paste or jelly. If the contact with the patient is reduced or if the jelly dries out, a high-current density area would result, increasing the probability for burns at the contact point.

Bipolar electrode systems use a two surface device (such as forceps, tweezers, pliers and other grasping type instruments) where two separate surfaces can be brought
20 together mechanically under force. Each opposing surface is connected to one of the two source connections of the electrical generator. Then the desired object is held and compressed between the two surfaces. Then when the electrical energy is applied, it is concentrated (and focused) so that tissue can be cut, desiccated, burned, killed, stunned, closed, destroyed or sealed between the grasping surfaces. Assuming the instrument has
25 been designed and used properly, the resulting current flow will be constrained within the target tissue between the two surfaces. The disadvantage of the conventional bipolar system is that the target tissue must be properly located and isolated between these surfaces. To reduce extraneous current flow the electrodes can not make contact with other tissue, which often requires visual guidance (such as direct visualization, use of a
30 scope, ultrasound or other direct visualization methods) so that the target tissue is

properly contained within the bipolar electrodes themselves, prior to application of electrical energy.

In recent years, considerable efforts have been made in refining sources of RF or electrical energy, as well as devices for applying electrical energy to specific targeted tissue. Various applications such as tachyarrhythmia ablation have been developed, whereby accessory (extra) pathways within the heart conduct electrical energy in an abnormal pattern. This abnormal signal flow results in excessive, and potentially lethal cardiac arrhythmias. RF ablation (as it is called) delivers electrical energy in either a bipolar or unipolar configuration utilizing a long catheter, similar to an EP (electrophysiology) catheter. That catheter (consisting of a long system of wires and supporting structures normally introduced via an artery or vein which leads into the heart) is manipulated using various guidance techniques, such as measurement of electrical activity, ultrasonic guidance, and/or X-ray visualization, into the target area. Electrical energy is then applied and the target tissue is destroyed.

A wide variety of technology in the development of related systems, devices and EP products has already been disclosed. For example, US Pat. No. 5,397,339 (issued March 14, 1995) describes a multipolar electrode catheter, which can be used to stimulate, ablate, obtain intercardiac signals, and can expand and enlarge itself inside the heart. Other applications include the ability to destroy plaque formations in the interior of lumens within the body; using RF energy applied near (or at the tip of) catheters such as described in US Pat. No. 5,454,809 (issued Oct. 3, 1995) and US Pat. No. 5,749,914 (issued May 12, 1998). In these applications a more advanced catheter (though similar to the EP catheters (described above)) contains an array of electrodes that is able to selectively apply energy in a specific direction. This device allows ablation and removal of asymmetric deposits/obstructions within lumens in the body. In that application, guidance may also be applied in various forms. US Pat. No. 5,098,431 (issued March 24, 1992), discloses another catheter based system for removing obstructions from within blood vessels. Parins in US Pat. No. 5,078,717 (issued Jan. 7, 1992) discloses yet another catheter to selectively remove stenotic lesions from the interior walls of blood vessels. Auth in US Pat. No. 5,364,393 (issued Nov. 15, 1994) describes a modification of the above technologies whereby a guide wire (a much smaller wire which goes through an

angioplasty device and is typically 110cm or longer) has an electrically energized tip, which creates a path to follow and thus guides itself through the obstructions.

In applications of a similar nature, catheters which carry larger bursts of energy (for example from a defibrillator) into chambers of the heart have been disclosed. These catheters are used to destroy both tissues and structures as described in Cunningham (see US Pat. No. 4,896,671 issued Jan. 30, 1990) that describes a catheter for delivery in electroshock ablative therapy.

One application of this technology would induce the elimination of glabellar furrowing by interrupting the conduction of nerve signals to muscles causing frown wrinkles. Traditional treatments have included surgical forehead lifts, resection of corrugator supercilli muscle, as described by Guyuron, Michelow and Thomas in *Corrugator supercilli muscle resection through blepharoplasty incision.*, Plastic Reconstructive Surgery 95 691-696 (1995). Also, surgical division of the corrugator supercilli motor nerves is used and was described by Ellis and Bakala in *Anatomy of the motor innervation of the corrugator supercilli muscle: clinical significance and development of a new surgical technique for frowning.*, J Otolaryngology 27; 222-227 (1998). These techniques described are highly invasive and sometimes temporary as nerves regenerate over time and repeat or alternative procedures are required.

More recently, a less invasive procedure to treat glabellar furrowing involves injection of botulinum toxin (Botox) directly into the muscle. This produces a flaccid paralysis and is best described in *The New England Journal of Medicine*, 324:1186-1194 (1991). While minimally invasive, this technique is predictably transient; so, it must be re-done every few months.

Specific efforts to use RF energy via a less sophisticated two needle bipolar system has been described in an article by Hernandez-Zendejas and Guerrero-Santos called *Percutaneous Selective Radio-Frequency Neuroablation in Plastic Surgery*, Aesthetic Plastic Surgery, 18:41 pp 41-48 (1994) They described a bipolar system using two needle type electrodes. Utley and Goode described a similar system in *Radio-frequency Ablation of the Nerve to the Corrugator Muscle for Elimination of Glabellar Furrowing*, Archives of Facial Plastic Surgery, Jan-Mar, 99, V1 P 46-48. Later they were granted

US Pat. No. 6,139,545 (issued Oct. 31, 2000), which fully described the two needle bipolar system. These systems were unable to produce permanent results (i.e. greater than a few months) because of limitations in the energy and their polar configurations and like with Botox, would have required periodic repeat procedures.

5 There are many ways of properly locating an active electrode near the target tissue and determining if it is in close proximity to the nerve. Traditional methods have included stimulation by using either unipolar and bipolar energy by means of a test pacemaker pulse prior to the implantation of a pacemaker or other stimulation device. A method of threshold analysis called the 'strength duration curve' has been used for many
10 years. This curve consists of a vertical axis (or Y-axis) typically voltage, current, charge or other measure of amplitude, and has a horizontal axis (or X-axis) of pulse duration (typically in milliseconds). Such a curve is a rapidly declining line, which decreases exponentially as the pulse width is increased. This curve is described on pp31ff in The Third Decade of Pacing, by Barold and Mugica (1982) and also on pp 245 in The
15 Biomedical Engineering Handbook" CRC Press, IEEE Press, Ed by J.D. Bronzino, (1995).

Various stimulation devices have been made and patented. The process of stimulation/ablation using a two-needle system is disclosed in US Pat. No. 6,139,545 (Oct. 31, 2000). This process is described in reverse, where the area not desired for
20 detection of ancillary tissue is treated with stimulation then ablation. The process is best described in US Pat. No. 5,782,826 (issued July 21, 1998).

The new method and device of this preferred embodiment also uses (among other potential methods of locating the tip of the electrode in proximity to the target nerve)
25 stimulation, followed by ablation. In this process the energy is delivered via the single puncture MIS system (as later described). This unique technology and resulting device is a single needle that contains both electrodes. It will access the site via a single puncture and will be used with MIS surgical techniques. It will also have features that provide for placement and have substantial added benefits, which are described later in this
30 document.

SUMMARY OF THE INVENTION

The primary aspect, of the present invention, is to provide a single-needle type puncture entry way for bi-polar electrodes for delivering RF energy near the nerve (to terminate signal flow), in a minimally invasive procedure. Other aspects of this invention will be apparent from the appended claims, descriptions and drawings that follow.

Important aspects of this invention include:

- A visible probe tip illumination to aide in positioning;
- A hollow lumen for delivery of medication, often, but not limited to, anesthetic;
- 10 Delivery of ionizing radiation, via laser, to probe tip for direct energy delivery;
- Coordination of ionizing radiation and RF energy delivery;
- Unique probe identification;
- Prior usage detection to eliminate potential contamination or unauthorized re use;
- Procedure power settings matched to probe internal identification;
- 15 Direct reading of ablation probe temperature and impedance;
- Pre-stored arbitrary amplitude modulation envelopes with multi-frequency for controlled energy delivery;
- Controlled metered energy delivery determines permanence;
- Multi-frequency operation for optimal power delivery;
- 20 Dynamic impedance matching for optimal power delivery;
- Integrated dielectric insulator as fiber optic for illumination, thus reducing diameter;
- Auxiliary nerve locator probe;
- Depth markings on auxiliary probe;
- Auxiliary probe needle shaft insulation;
- 25 Dual needle tipped auxiliary probe;
- Electronic guidance of ablation probe to auxiliary probe;
- Electronic guidance measures and displays current proportional probe distances;
- Electronic guidance variable frequency audio tone proportional to distance/sense current;
- 30 Electronic guidance variable amplitude audio tone proportional to distance/sense current;

Electronic guidance variable frequency/flash rate of ablation tip illumination proportional to distance/ sense current;

Illumination of florescent-tagged marker;

Detection of florescent emission of tagged marker;

5 Simultaneous illumination of florescent-tagged marker and emission detection;

Simultaneous illumination of florescent-tagged marker by means of a tunable laser;

Integrated hollow biopsy electrode for florescent-tagged tumor sampling;

Integrated hollow electrode for medication delivery to tagged tumor;

10 Integrated hollow electrode for photo-medication delivery to tagged tumor with illumination activation source; and

Another aspect of the invention is a probe usage register to reduce or eliminate chance of patient cross contamination.

This invention is an improved device (and method for its use) that will allow the
15 physician to terminate signal flow through nerves, in a minimally invasive manner, by requiring only a single-needle type puncture. Said method and device would allow for a reduced patient recovery time; the patient would be awake during the procedure; using only a local (or very little) anesthetic; have a substantially reduced risk of infection; less of a risk of intensive care (or hospital stay), and subsequently, a reduced associated costs.
20 Inasmuch, the patient would more rapidly return to a normal lifestyle as compared to many procedures requiring open surgery.

This single-puncture device (hereafter called 'single-pass') presents an improvement over conventional uni-polar systems because it does not require a separate return electrode, which is attached to the patient at a remote site and subsequently must be
25 maintained during the surgical procedure. Also, it represents an improvement over bi-polar electrodes and earlier two needle systems, because it concentrates the energy specifically at the desired location (by use of one active electrode) and when ablation areas need to be precisely focused this device may best accomplish that task.

The device (and the methods needed to operate it) can be used to terminate, stop or
30 inhibit (on a temporary, semi-permanent or even permanent basis) the transmission of nerve signals to the muscles, organs and receivers of nerve signals, which convey activation, perception, pain signals or other nervous impulses. In the preferred

embodiment, the active electrode (or the probe/needle tip) may be positioned by various guidance and/or sensing means. This includes (but is not limited to) ultrasound, traditional pace/sense (apply stimulating signals and observe placement of the electrode in proximity to the target nerve), manual palpitation, proper anatomical positioning, X-ray, CT, MRI, PET or other radiation or emission type imaging means, fiber-optic video, external location (and marking) and subsequent location by illuminating the probe tip or by other similar means.

In addition to the 'single-pass' needle, the complete system shall include an intelligent external energy generator, which can be used either by programmed or manual control. The manual control may be mitigated (or limited for the protection of the patient) by means of various sensors including (but not limited to) impedance (and the change in impedance), temperature (and the change in temperature), normal voltage (or current) regulation, etc. Said generator will generate RF energy in the frequency range of 50Khz to 2.5Mhz, in a controlled manner.

The generator will also be usable under program control. Said programming will deliver a predetermined "bolus" (or packet) of electrical energy, whereby the dose is adjustable (within limits) by the physician proportional to the desired effect. This bolus will be predetermined in clinical studies and may have preset parameters such as minimal effect, average effect, maximum effect, corresponding to a low, normal and high-output level. The output cycle will be activated by the physician via footswitch, a button on the probe itself, voice or other similar method of activation methods. When the bolus output is activated it may be terminated (at any time) by releasing activation means (i.e. the footswitch, button or the like). However, it will provide output no greater or longer than the activation device is held down, and will also be limited to the length of time and dosage preset. To deliver a second packet of energy, the activation mechanism must be released for (an internally set) time period before another packet of energy may be delivered. Also, because this technology may be used in various applications (e.g. plastic surgery, spinal nerves causing back pain, and other applications where terminating signal flows through nerves is desired) the delivery systems (i.e. single-pass needle or probe, and the generator required to power same) may be of differing sizes, surface areas or mechanical configurations. Some may even require a substantially different amount or

type of energy packet. Program setting and preferences made be controlled for the different applications by providing a specific hand tool device that would then contain a coded circuit, connector or other means of providing identification to the generator so that it may deliver the required energy packets automatically for the different applications or methods.

The methods of ablation may include both a linear or circular zone. The effective ablation area may be modified by "laying down" a series of individual ablation zones, thus creating a line of ablated tissues. This would be possible by withdrawing, inserting, and/or moving the active tip while ablating in the successive zones, which would expanding the liner component of any lesion produced. In the alternative, the effective zone of ablation could be extended circumferentially by manipulating the tip during the ablation cycle in small circles, thereby mechanically moving the tip enlarging the effective zone of ablation.

BRIEF DESCRIPTION OF THE DRAWINGS

- FIG 1 Bi-Polar Driver System
- 5 FIG. 2 Schematic diagram of the bi-polar needle
- FIG. 2A Schematic diagram of the split bi-polar needle
- FIG. 3A Magnified side view of conical bi-polar probe.
- FIG. 3B Magnified side view of hollow chisel bi-polar probe.
- FIG. 3C Magnified side view of tapered conical bi-polar probe.
- 10 FIG. 3D Magnified side view of split conical bi-polar probe.
- FIG. 4 Schematic diagram of the bi-polar driver system
- FIG. 5A Ablation Procedure without Auxiliary probe
- FIG. 5B Ablation Procedure with Auxiliary probe
- Fig 6. Side view Hybrid bi-polar needle for nerve ablation.
- 15 Fig. 6A Side view Hybrid bi-polar needle for tumor ablation.
- Fig. 7 Side view of auxiliary nerve probe.
- Fig. 7A Side view of auxiliary dual-tipped nerve probe.
- Fig. 8 Side view of guided ablation procedure with auxiliary nerve probe(s).
- FIG. 9 Sample electro-surgery waveforms.
- 20 FIG 10 Side view of visually guided ablation procedure.
- FIG 11-11A Controller and probe data base structure

Defined below are the terms used here within:

MEDICAL TERMS

- 5 Corrugator supercili muscles - skeletal muscles of the forehead that produce brow depression and frowning
- Cerepressor anguli oris - skeletal muscle of the corner of the mouth that produces depression of the corner of the mouth
- Depressor labii inferioris - skeletal muscle of the lower lip that causes the lip to evert and depress downward
- 10 Dystonias - medical condition describing an aberrant contraction of a skeletal muscle which is involuntary
- Frontalis - skeletal muscle of the forehead that produces brow elevation or raising of the eyebrows
- Hyperhidrosis - condition of excessive sweat production
- 15 Masseter - skeletal muscle of the jaw that produces jaw closure and clenching
- Mentalis - skeletal muscle of the lower lip and chin which stabilizes lower lip position
- Orbicularis oculi - skeletal muscle of the eyelid area responsible for eyelid closure
- Orbicularis oris - skeletal muscle of the mouth area responsible for closure and competency of the lips and mouth
- 20 Parasympathetic - refers to one division of the autonomic nervous system
- Platysma myoides - skeletal muscle of the neck that protects deeper structures of the neck
- Platysma - same as above
- Procerus muscles - skeletal muscle of the central forehead responsible for frowning and producing horizontal creasing along the nasofrontal area
- 25 Procerus - same as above
- Rhinorrhea - excessive nasal mucous secretions
- Supercilli - a portion of the corrugator muscle that sits above the eyelids
- Temporalis - skeletal muscle of the jaw that stabilizes the temporomandibular joint
- 30 Zygomaticus major - skeletal muscle of the face that produces smiling or creasing of the midface

ELECTRICAL TERMS

	ADC:	Analog to digital converter
	ASCII:	American standard of computer information interchange.
	BAUD:	Serial communication data rate in bits per second.
5	BYTE:	Digital data 8-bits in length
	CHARACTER:	Symbol from the ASCII set.
	CHECKSUM:	Numerical sum of the data in a list.
	CPU:	Central processing unit.
	EEPROM:	Electronically erasable programmable read only memory.
10	FLASH MEMORY:	Electrically alterable read only memory. (See EEPROM)
	GUI:	Graphical user interface.
	HEXADECIMAL:	Base 16 representation of integer numbers.
15	I2C BUS:	Inter Integrated Circuit bus. Simple two-wire bi-directional serial bus developed by Philips for an independent communications path between embedded ICs on printed circuit boards and subsystems. The I2C bus is used on and between system boards for internal system management and diagnostic functions.
	INTERRUPT:	Signal the computer to perform another task
	PC:	Personal computer.
20	PWM:	Pulse-width modulation
	ROM:	Read only memory.
	WORD:	Digital data 16-bits in length

DETAILED DESCRIPTION OF OVERALL OPERATION

25 This section provides information on the overall operation of this system. Figure 1 has two main components and one optional component, which are the energy generator 400, the probe 371 (alternate probes are described in Fig. 3A-D) and optionally probes 771 or 772 that may be used.

30 In normal operation, the novel probe 371 would combine a unique bipolar configuration in a single MIS needle, is inserted into the patient using MIS techniques. The probe, which may contain and/or convey various functions described later, is initially guided anatomically to the region of the anticipated or desired location. Various means

of locating the tip **301** are utilized of placing the zone of ablation in the proper area to interrupt signal flows through the nerve **101**.

DETAILED DESCRIPTION OF DEVICE OPERATION

5 This section refers to the drawings to describe use of the probe. There are many combinations of electrode diameters and tip shapes are possible. The 'novel' probe performs a variety of functions, such as stimulation, optical and electronic guidance, medication delivery, sample extraction, and controlled ablation. This bi-polar electrode is designed as a small diameter needle inserted from a single point of entry thus
10 minimizing scarring and simplifying precise electrode placement. This low cost, compact design provides a new tool to the art.

Probes may emit fiber optic illumination for deep applications using electronic guidance as taught in figure **1** and **8**. The invention offers a simple low cost ablation probe that is capable of performing precise ablation while minimizing damage to nearby
15 tissue structures. The metered ablation energy and precise probe targeting give the practitioner a tool is also not available in prior art. The practitioner has unprecedented control of treatment permanence in a minimally invasive procedure. Such a procedure is typically performed in less than one hour with only local anesthetic and would require no stitches or chemicals common to prior medical art.

20

STIMULATION / ABLATION

First the probe electrode **301** must be in the desired location relative to the target nerve **101** (**FIG. 4**), then the user initiates the treatment via switch(s) **410** and **310** using the selected power setting **404** (**FIG. 4**). The controller configures the generators **411**
25 (**FIG. 4**) and **412** to the amplitude frequency and modulation envelope, delivering 50 KHz – 2.5 MHz of 5 to 500 watts of available energy. The summing junction **413** combines the RF outputs as the application requires and passes them to the pulse-width modulator **415** for output power control. The output of modulation generator **420** is applied to the multiplier **415** with radio frequency RF signals **422** and **423**. This permits
30 complex energy profiles to be delivered to a time variant non-linear biologic load. All of

these settings are based on the information provide to the generator by the installed probe 371 the selected power 404 settings, and the modulation envelope 420 (Fig. 4) settings, which are then loaded by the generator 421.

For example, both a high amplitude sine wave 910 (FIG. 9), used for cutting, and a pulse-width modulated (or PWM) sine wave 920, used for coagulation, are well known to electro-surgery art. Precise power rates and limits of average total power are controlled via integrator 435 minimizing damage to nearby structures or burning close to the skin for shallow procedures. Where nearby structures 111(FIG. 2A) are too close to be avoided by electrodes such as 371 (FIG. 3), 372 (FIG. 3A), and 372 (FIG. 3B), additional probe geometries as taught in FIG. 3D, 6 and 6A offer novel methods to direct energy and limit ablation to a smaller region, thereby avoiding other structures. For safety a hardwired switch 436 disables the power amplifier in the event of a system fault, the probe is unplugged or over power condition, thus protecting both the patient and practitioner.

The output of the modulator 415 is applied to the input of the power amplifier 416 section. The power amplifier's 416 outputs are then feed into the impedance matching network 418, which provides dynamic controlled output to the biologic loads that are highly variable and non-linear, and require dynamic control of both power levels and impedance matching. The tuning of the matching network 418 is performed for optimal power transfer for the probe, power level, and treatment frequencies settled. The system's peak power is 500 watts for this disclosed embodiment. Precise control is established by the proximity of the tip and the control loops included in the generator itself. The final energy envelope 420 is delivered to probe tip 301 and return electrodes 302.

This precise control of energy permits extension of the ablation region(s), 140 and 1203 (FIG. 10), and the duration of treatment efficiency. Low or medium energy settings 404 permit temporary nerve-conduction interruption for 3-6 months. Higher energy settings at 404 may result in a longer nerve conduction interruption of 1 year to permanent. In the prior art, procedures had little control over duration of termination of such signal flow through the nerve. This invention gives the practitioner enhanced

control of such duration. Patients can evaluate controlled temporary treatment before choosing longer or permanent treatment options.

A low energy nerve stimulator 771 has been integrated into the system to assist in more precise identification of nearby structures and for highly accurate target location.

5 Lastly, additional sensors, such as temperature 311, voltage, frequency, current and the like are read directly from the device and/or across the communications media 403 to the probe.

DIRECTED ABLATION

10 In addition to the substantial radially-symmetric ablation patterns with probes as taught in 371 (FIG. 3) and 372, switching or dividing ablation power to multiple electrodes (FIG. 3D) can generate a asymmetric ablation zone. This high intensity source 608 with probe 610 (FIG. 6 and 6A) minimizes damage to nearby structures 111 or the burning of skin 330 in shallow procedures. Also, FIG. 2A and 3D identifies probe
15 configurations for selective or asymmetric ablation.

POWER FEEDBACK

The power amplifier output 430 and buffered the feedback signals 437 are connected to an Analog to Digital converter (or ADC) 431 for processor analysis and control. Said
20 signals 437 control power modulation 420 settings and impact the impedance matching control signals 419. This integrated power signal 437 is recorded to the operating-condition database (FIG. 11) for later procedure review. This power level is also compared to reading taken from the probe 1492 (FIG. 11A) as compared against procedure maximums, which if exceeded will in turn disable the amplifier output, thereby
25 protecting the patient from error or equipment fault. Similarly, limits from the probe and generator sensors such as temperature 330 are also used to terminate or substantially reduce the modulated power levels and ultimately the procedure.

PROBE IDENTIFICATION

At power startup, the controller **401**(**FIG. 4**) reads the probe status and internal identification kept within the probe itself **331** (and **371**) via serial communications **403** (or bus). Serial communications is used because it is commonly available to most single-
5 chip microprocessors. This or similar methods (e.g. I2C, or SPI) may be used, but this disclosed embodiment will use serial for its simplicity. Serial communications **403** permits the generator to address and control EEROM memory **331**, temperature sensors **330**, processors, ADC and DACs within the single-chip microprocessor embedded in the probe itself. The user selects the desired power setting **404** and based on probe
10 identification read from the EEROM or microprocessor **331** makes the appropriate configurations. The probe **371** is connected via cable **1334** (**FIG. 1**) to control unit **101** or generator. This probe is not intended for multiple procedural use. So to prevent such use of the probe, the controller **401** (**FIG. 4**) reads the stored time register from ID memory module **331**. If the probe's initialized time **1467** (**FIG. 14**) is zero, the current
15 real-time clock **482** value is written to probe's **331**'s initial time register via serial bus **403**. If time read on module **331** is non-zero, the probe's initial time register is added to two(2) times the procedural time (based on the probe type) **FIG.14 1420**. If that value when compared to current real-time clock **482**, is less than current time, the controller will alert the practitioner via display **450**, speaker **451** and, flashing probe illumination
20 **608**, that the procedure will be terminated and the probe rendered invalid.

The controller **401** also verifies selected procedure **1415** (**FIG. 11**) for compatibility with installed probe. If incompatible, the user is also prompted to select a different power setting **404**, procedure, or probe **371**. If probe **371** matches power setting **404**, the system enables power amplifier **416**, guide light source **408**, and low-voltage nerve
25 simulation **732**. Both of these procedures are enforced by a mandatory "hand shake" protocol and the serialized information, which must be present and properly verified by the electronic circuitry for a procedure to be instituted. During a clinical procedure, information is required to be conveyed by the embedded electronics contained within the probe, which provides another way of enforcing this protection and thus again preventing
30 unauthorized re-use. The ultimate goal is prevent cross-contamination between patients. The probe will accomplish this by being unique, serialized, and given the above

procedures. Once plugged in, the probe will enter the serial number into the data logging system via the serial bus 403 and circuit logic will thereafter prevent re-use of the probe and cross-contamination that would occur. Further, this scheme will prevent the use of unauthorized third party probes, for they will not be activated, preventing potential inferior or uncertified probes from being used and presenting potential danger to the patient.

NERVE TARGET LOCATION TOOLS

Prior to treatment, the practitioner may use auxiliary probe 771(FIG. 4), to locate target 101 and nearby structures 111 as taught in FIG. 4, 7, 7A, 8, and 10. When needle 771 is in place, the practitioner may locate and place a mark or marks on the surface of the skin 755 (see FIG. 7 and 8) or leaves auxiliary probe 771 in place. For shallow sub-cutaneous procedures, probe tip illumination 448 from source 408 is visible to practitioner aiding in probe placement to pre-marked location.

LOCATION VIA FLORESCENCE MARKER DYE

In other procedures, whereby somewhat larger targets are sought, such as more diffuse nerve structures or small areas of abnormal growth (e.g. such as cancer) the injection of specially designed dyes that attach to target structures are used, as taught in FIG. 6A. The probe 610 (FIG. 6) is moved into the proximity of the target 671. The light source 608 illuminates quantum-dot/dye tagged antibody 670. The dye fluoresces 675 at a frequency/wavelength of a particular material and will typically emit light in the visible to infrared (or IR) or potentially other wavelength regions. The return fiber(s) 680 deliver emissions 675 to the detector 478 for measurement and the result is then displayed on bar graph 554 (FIG. 1) and/or an audio tone sounded via speaker 451 based on proximity. Visible and IR light emissions propagate over limited distances permitting additional external detectors 678 to be used for shallow targets just under the skin 330. Location via this method is similar to the electronically guided probe method taught in FIG. 8 where probe 610 movement maximizes the signal output when in close proximity. IR emissions propagate and can permit deeper (typically several centimeters) detection with optional additional external sensors 678. Unfortunately, many dyes fluoresce in the

visible region making external detection imposable for deep targets or when obscured by bone. However, probe **610** (**FIG. 6A**) solves this problem by integrating target illumination **674**, emission **675** detector, ablation, biopsy, and medication delivery in single compact probe. Electronic probe guidance (**FIG. 8**) if required is used in combination with florescence detection to rapidly locate target. The instant invention offers a minimally invasive system for locating and treating small/deep tumors and other tissue that are to be ablated, destroyed or removed.

ELECTRONIC PROBE GUIDANCE

Low energy nerve stimulation current **810** (**FIG. 8**) assist in locating desired treatment region and avoiding nearby structures. Probe **771** is selectable between nerve stimulator and current measurement to/from auxiliary probe tip **702**(**FIG. 8**). Return electrode **736** provides a return path for local ground **735**. Ablation probe switch **367** selects low-energy stimulator/receiver and high-energy ablation to/from probe **372**.

Amplitude of measured guidance current **811** and light **478** are transmitted to display **554**, and audio feedback **452** through the speaker **451**.

OPTICAL PROBE GUIDANCE

Disclosed invention provides optical sources **408** that aid in probe placement (**FIG. 10**) by supplementing stimulation source **732** and acting as preliminary guide. Probe **771** is selectable between nerve stimulator or current **811** measurement and to or from the auxiliary probe tip **702**. The ablation probe switch **367** selects low-energy stimulator/receiver or high-energy ablation to or from probe **371**, **372**, **373**, and **374**. In this mode, the physician operator will have previously placed marks **755** on the surface of the skin by various means described. The physician operator **775** will then see the tip when the **448** if the optical illumination is turned on. It **448** will provide a bright spot under the skin indicating the location of the tip in relation to the marks **755**. The physician **775** will then guide the probe tip **301** into precise alignment under these marks **755** so as to enable ablation of that target tissue **101**.

DATA AND VOICE

Real-time engineering parameters are measured such as average power 437, luminous intensity 478, probe current 811, energy 438 and, temperature 330 to be recoded into
5 USB memory 438. Simultaneously, the internal parameters disclosed such as frequency 423, modulation 420 and such are recoded into USB memory 438 as well. Additionally probe, patient, and procedure parameters (FIG. 11) are written to local storage 438. The practitioner dictates text and voice notes via microphone 455, which are saved to memory 438 (FIG. 1). All data and records are time stamped using the real-time clock 482. This
10 permits detailed post procedure graphing and analysis.

DATA TRANSFER

At procedure conclusion, the system transfers the data 438 recorded to the USB removable memory 1338 and to a file server(s) 1309 and 1307. In the disclosed
15 embodiment, data transfer is performed over Ethernet connection 480. Probe usage records 1460(FIG. 11) that are stored in local memory 438 are then written to removable memory module 1338. Parallel records are mirrored to local storage 1309 and remote server 1306 storage 1307 via Ethernet connection 480 or similar means. Sensitive records are encrypted and transferred via secure network connection and also written to
20 removable module 1320. The database contained on the remote server tracks the following information: equipment by manufacture, probe accessory inventory, usage, billing, repair/warranty exchange information, and program recorders. As a system 400 is certified for new procedures 1410 (FIG. 11), the relational databases are automatically updated to reflect new billing/procedure codes 1416, potential power settings 1417 and
25 the like. This insures that the equipment is current and alerts the practitioner to new probes / procedures as they are developed and certified.

DETAILED DESCRIPTION OF THE DRAWINGS

Before explaining the disclosed embodiment of the present invention in detail, it is to be understood that the invention is not limited in its application or to the details of the particular arrangement shown. The invention is capable of other embodiments. Further, the terminology used herein is for the purpose of describing the probe and its operation. Each apparatus embodiment described herein has numerous equivalents.

10 FIG. 1 Bi-Polar Driver System

Figure 1 identifies the two required components of the system, various modules and optional items. The two components always utilized during a procedure will be the energy generator/controller/data storage device **400** and probe **371**. **400** contains advanced electronic systems capable of recognizing a properly authorized probe, preventing re use of a previously used probe, generating appropriate energy as described, performing safety checks, storing data, and other functions as described. Main functions of **400** may include, but not be limited to, generation of light, generation of location-stimulation currents, generation of ablation energies, data logging, storage, communication and retrieval, and other functions critical to a MIS procedure. Probe **371** and its various forms are single puncture bipolar surgical tools that may be used in identifying proper location of its tip **301**, in relation to target tissue 101 which is desired to be ablated, modified or destroyed. Probe **771** and its various derivatives may optionally be used to assist in locating and properly positioning tip **301** of probe **371**.

25 FIG. 2 Isometric view of the bi-polar probe

Bi-polar probe **310** represents probes **371**, **372**, **373** shown in Figures **3A-C** with exception to type of needlepoint on the probe. Figure **3D** varies from the other because it has a split return probe. Bi-polar probe **310** (not drawn to scale) consists of insulating dielectric body **309** made from a suitable biology inert material, such as Teflon, PTFE or

other insulative material, covering electrode **302** except for where **302** is exposed as a return electrode. Conductive return electrode **302** tube is fabricated from medical grade stainless steel, titanium or other conductive material. Hollow or solid conductive tip electrode **301** protrudes from surrounding dielectric insulator **305**. Sizes of **309**, **302**, **305**, and **301** and its inner lumen (diameter, length, thickness, etc.) may be adjusted so as to allow for different surface areas resulting in specific current densities as required for specific therapeutic applications.

Hollow Electrode **301** often used as a syringe to deliver medication such as local anesthetic. Tip electrode **301** is connected to power amplifier **416** via impedance matching network **418** (**FIG. 4**). Return electrode(s) **302** delivers return current to power amplifier **416** via impedance matching network **418**. Dielectric insulator in the disclosed embodiment is a transparent medical grade polycarbonate acting as a light pipe or fiber optic cable. Light source LED or laser **408** (**FIG. 4**) provides illumination at the far end of the probe via fiber optic cable / transparent dielectric **305** for guiding the probe under the skin i.e. shallow procedures. In an alternate embodiment dielectric insulator is replaced with a plurality of optical fibers for viewing and illumination as taught in **FIG 6**.

Ablation regions **306** and **140** extend radially about electrode **301** generally following electric field lines. For procedures very close to skin **330** a chance of burning exists in region **306**. To minimize the chance of burning, a split return electrode probe **374** in **Figure 3D** is offered. Thereby concentrating the current away from region **306** to **140** or vice versa. In **FIG.2A**, insulator **307** splits the return electrode into two sections **302** and **303**, dividing return current ratio from 0-50%, which may also be selectively activated. Active electrodes are also split into two sections **301** and **311** so energy may be directed in a desired direction. This electrode configuration is identified on the proximal portion of the probe so the operator may position the needle and electrodes accordingly. **Figure 6** teaches a laser directed ablation for more precise energy delivery.

FIG. 2A Isometric view of split bi-polar probe.

The bi-polar probe **380** (not drawn to scale) consists of an insulating dielectric body **309** made from a suitable biologically inert material, such as Teflon PTFE or other

electrical insulation, that covers split return electrodes **302** and **303**. The disclosed conductive return electrodes **302** and **303** are fabricated from medical grade stainless steel, titanium or other electrically conductive material. Hollow or solid split conductive tip electrodes **301** and **311** protrude from the surrounding dielectric insulator **305**. The operation of the hollow/split conductive tip is very similar to probe tip **310** as taught in **FIG. 3D**. Ablation regions **1203** (**FIG. 10**) and **140 – 144** extend radially about electrode **301** generally following electric field lines. For procedures very close to skin **330** a chance of burning exists in region **306**. To minimize chance of burning a split return electrode probe **311** is used, thereby concentrating the current away from region **306** to **140**. For procedures where there is a risk to nearby structures **111**, the ablation region **1203** must be a non-radial ablation zone. The disclosed split electrode **380** permits dividing or splitting energy delivered to electrode pairs **301/302** and **311/303**. The disclosed division or ratio between pairs is 0-100%. Dual amplifiers or time multiplexing/switching main amplifier, **416** located between electrode pairs, directs energy to target **101** avoiding **111**. This simple switch network reliably ratios electrical energy while minimizing damage to nearby structures.

FIG. 3A Conical Bi-polar Needle

Bi-polar probe **371** discloses conical shaped electrode **301** and tip **351** for minimally invasive single point entry. Probe diameter **358** is similar to a 20-gage or other small gauge syringe needle, but may be larger or smaller depending on the application, surface area required and depth of penetration necessary. In disclosed embodiment, electrode shaft **302** is **30mm** long with approximately **5mm** not insulated. Lengths and surface areas of both may be modified to meet various applications such as in cosmetic surgery or in elimination of back pain. The conductive return electrode **302** is fabricated from medical grade stainless steel, titanium or other conductive material. The dielectric insulator **305** in the disclosed embodiment is a transparent medical grade material such as polycarbonate, which may double as a light pipe or fiber optic cable. The high intensity light source **408** LED/laser (**FIG. 4**) provides guidance Illumination **448** at working end of probe. The illumination source modulation/flash rate is proportional to the received stimulation current **810** as taught in **FIG. 8**. A small diameter electrode permits a

minimally invasive procedure that is typically performed with local anesthetic. This configuration may contain lumens for delivery of agents as described elsewhere.

FIG. 3B Hollow Chisel

5 The hollow chisel electrode **352** is often used as a syringe to deliver medication such as local anesthetic, medications, / tracer dye. The hollow electrode may also extract a sample. Dielectric insulator **305** in the disclosed embodiment is a transparent medical grade polycarbonate and performs as a light pipe or fiber optic cable. The novel dual-purpose dielectric reduces probe diameter and manufacturing costs. Light source **408**,
10 typically a LED or laser (**FIG. 4** not shown), provides Illumination **448** at the working end of probe. It provides an illumination source for guiding the probe under the skin. A second embodiment, as taught in **FIG. 6**, dielectric insulator is replaced/combined with plurality of optical fibers for viewing / illumination.

15 FIG. 3C Tapered Conical

 The bi-polar probe **373** discloses a tapered conical shaped probe for minimally invasive single point entry. It is constructed similarly to probe **371** as taught in **FIG. 3A**. Probe tip is not drawn to scale to teach the tip geometry. In disclosed embodiment, electrode **301** is approximately 5mm long and fabricated from medical grade stainless
20 steel but may be of various lengths to accommodate specific application and surface area requirements. The solid tapered conductive tip electrode **353** protrudes from tapered dielectric insulator **305**. Transparent dielectric insulator **305** also performs as light pipe or fiber optic cable terminated to high intensity light source **408** (**FIG. 4**) providing illumination **448**. The electrode assembly is mounted in an ergonomic handle **388** (which
25 has not been drawn to scale). Handle **388** holds ablation on/off switch **310**, ablation/stimulation mode switch **367**, identification module **331** and terminations for cable **1334** (**FIG. 13**). Temperature sensor **330** (located close to tip) monitors tissue temperature.

FIG. 3D Split Conical Bi-polar Probe

Description of this probe is described in both drawings **2A** and **3D**. Bi-polar probe **374** (not drawn to scale) consists of insulating dielectric body **309** made from a suitable biologically inert material, such as Teflon, that covers split return electrodes **302** and **303**.

5 Conductive return electrodes **302** are fabricated from medical grade stainless steel, titanium or other suitable conductive material. Hollow or solid split conductive tip electrodes **301** and **311** protrude from surrounding dielectric insulator **305**. Their operation is very similar to probe tip **380** as taught in **FIG. 2A**. Solid tapered conductive tip electrodes **311** and **301** protrude from transparent dielectric insulator **305**. Dielectric
10 insulator **305** also performs as a light pipe or fiber optic cable terminated to high intensity light source **408** providing illumination **448**.

Probe handle (not drawn to scale) encloses memory module **331**, on/off switch **310** and mode switch **367**. Temperature sensor **330** (located close to tip) monitors tissue temperature. Split electrode **380** (**FIG. 2A**) permits dividing or splitting energy delivered
15 to electrode pairs **301/302** and **311/303**. Dual amplifiers or time multiplexing/switching main amplifier **416** are located between electrode pairs directing energy to target **101** avoiding **111** creating asymmetric ablation volume. A small diameter electrode needle is injected from a single point of entry minimizing scaring and simplifying precise electrode placement.

20 Connections consist of a tapered dielectric sleeve **309** covering the ridged stainless electrode tube **302**. Insulating sleeve **309** is made from a suitable biologically inert material, which covers electrode **302**. Dielectric **305** insulates conical tipped electrodes **351** and **301**.

25 FIG. 4A Schematic diagram of the bi-polar driver system.

See section Detailed Description of Device Operation.

FIG 5A Ablation Procedure (without auxiliary probes)

Ablation probe **371** is inserted and directed anatomically into the area where the
30 target nerve to be ablated (**Box 531**) is located. Test current **811** is applied (**Box 532**). If

probe is located in the immediate proximity of the target nerve a physiological reaction will be detected/observed (Example: During elimination of glabellar furrowing, muscle stimulation of the forehead will be observed). If reaction is observed, then a mark may optionally be applied on the surface of the skin to locate the area of the nerve. Power is applied (**Box 535**) in an attempt to ablate the nerve. If physiological reaction is not observed, (**Box 534**) the probe will be relocated closer to the target nerve and the stimulation test will be repeated (**Box 536 & 537**). If no physiological reaction is observed, the procedure may be terminated (**Box 544**). Also, the probe may be moved in any direction, up, down, near, far, circular, in a pattern, etc. to create a larger area of ablation for a more permanent result.

In **Box 537**, if stimulation is observed again, then the ablation power may be set higher (**Box 538**), alternatively, as mentioned, the needle may be moved in various directions, or a larger dosage of energy may be reapplied, to form a larger area of ablation for more effective or permanent termination of signal conduction through the nerve. After delivery of power (**Box 540**), stimulation energy may be applied again (**Box 541**). If there is no stimulation, the procedure is completed (**Box 544**). If there is still signal flow through the nerve (stimulation or physiological reaction) then the probe may be relocated (**Box 542**) and the procedure is started over again (**Box 533**).

FIG. 5B Flow chart of visually guided ablation procedure using auxiliary probes such as 771 and 772.

Auxiliary probes 771 and 772 (**FIG. 7 and 7A**) provide a method to quickly and accurately locate target structure 101 and subsequently mark target location 755.

Auxiliary probes may be much smaller (like acupuncture needles) than ablation probes.

Structures are marked typically with an ink or similar pen allowing the illuminated ablation probe 371 or other ablation probe to be quickly guided to mark 755. Optionally, non-illuminated probes may be used allowing the practitioner to simply feel for the probe tip. For deep structures, probe 771(**FIG. 8**) is employed as an electronic beacon. Small current 811, which is similar to the stimulation current but smaller, from probe tip 702 is used to guide ablation probe 372 (**FIG. 8**)

Operation 530 (FIG.5B) inserts auxiliary probe 771 or 772 (FIG. 7 and 7A) thru skin 330 and muscle layer(s) 710 near nerve 101. Target 101 depth 766 is measured (FIG.7 and 7A) using auxiliary probe markings 765. Decision 533 checks if the probe is in position if not adjustments are performed in 534. Operation 532 enables nerve simulation current 811. When muscle stimulation is obtained or physiological reaction is obtained, Auxiliary probe tip is in place. Depth may be noted by reading marks 765 and location marks 755 may be made in operation 535. With the probe in position under mark in operations 536 and 537, operation 538 sets power level 404 and closes ablation switch 410. Alternatively, stimulation may be applied directly from the ablation probe as taught elsewhere. Operation 540 and controller 401 set generator 411 (FIG. 4) frequencies, modulation 420 envelope and enables power amplifier 416 to deliver preset ablation energy. Region 1203 (FIG. 10) shows the general shape of the ablation region for conical tip 301 for example.

Between each ablation, procedure 540 (FIG. 5C) (nerve conduction) is tested in 541. Probe amplifier 416 delivers small nerve stimulation current 811 from electrode 301 or Auxiliary probe 771 or both. Based on the nerve conduction test 541 if the desired level of conduction is achieved the procedure is complete. Operation 542 moves the probe to the next position and repeats conduction test 541. If complete, the probe(s) is removed in operation 544. Number and ablation intensity/energy are set by the particular procedure and the desired permanence. The practitioner selects the procedure/power level 404 (FIG. 4) and controller 401 compares the installed probe via identification 331 (FIG. 4) for compatibility with selected procedure. The practitioner is alerted if the installed probe is incompatible with selected power range 404.

As an example and not a limitation, five ablation regions (140, 141, 142, 143, and 144) are shown in FIG. 10. Ablation starts with area 144, then the probe is moved to 143 and so on to 140. Alternatively, movement may be during insertion, moved laterally, in a circular manner or other manner to enlarge the area of targeted nerve destruction. Nerve responses may be tested after each ablation allowing the practitioner to immediately check the level of nerve conduction. Probe position and power adjustments are made before applying additional ablations if required. Accurate probe location tools and methods taught herein permit use of minimal ablation energy thereby minimizing damage

to non-target structures. This translates to reduced healing time and minimal patient discomfort. The instant invention gives the practitioner a new tool to perform a minimally invasive nerve conduction limiting procedure with the ability to select, temporary or permanent nerve conduction interruption with a new level of confidence.

- 5 This new tool offers a low cost procedure performed typically in office or outpatient setting often taking less than one hour with local anesthetic. In contrast to prior art where surgical procedures require stitches and longer healing intervals with limited control of permanence (nerve re-growth).

- 10 FIG. 6 Side view of the bi-polar probe 610 with enhanced laser targeting.

Probe insertion and placement is same as taught in FIG 3. Probe construction is the same as FIG. 3 with the dielectric 305 having embedded optical fibers 690 and 680 providing imaging / illumination. Additional fiber(s) 690-691 are illuminated by a high intensity laser source.

- 15 In special cases where target nerve 101 or ablation region 640 is in close proximity to second nerve 111 or skin 330 bi-polar probes 371 or 372 (FIG. 3) create an annular ablation region between electrodes 301 and/or 302, potentially damaging nearby structures such as other nerves 111. With probe 610 in the desired position, laser 608 (FIG. 4) is turned on target 670 (FIG. 6A) with illuminating fiber(s) 690. Fiber(s)
20 transmitting high intensity laser light to ionized region 640 is illuminated by fiber(s) 690. Simultaneous with laser illumination, RF energy 470 is delivered to electrodes 301 and 302. A relatively low impedance path is created by the high intensity laser illumination wherein RF energy will follow this newly created path. Thus very specific regions may be selected for ablation. By permitting operation at a lower power, energy is
25 concentrated where it is needed and eliminates or reduces damage to nearby structures such as skin 330 or nerves 111. Probe 610 improves on the already very precise ablation taught in FIG. 3 with the addition of a low power laser (or other type light source) and fiber delivery system. In the disclosed embodiment a diode pumped Nd:YAG (Neodymium Doped Yttrium Aluminum Garnet) laser is offered as an example and not a
30 limitation.

FIG. 6A Side view is the florescence emission guided hybrid bi-polar tumor probe.

Probe construction is similar to FIG. 3A and 6 with dielectric 305 embedded with a plurality of optical fibers 380, 690, and 680 for illumination detection / imaging. These

enhanced systems and processed augments the selective nature of previously disclosed probes. Fiber(s) 690-691 are illuminated by a high intensity light source(s) 608 which is typically a tunable laser or UV LED. Source(s) 608 (FIG. 4) provides illumination for tagged marker(s) 670 in the disclose embodiment where a tunable laser is employed.

Excitation/illumination wavelength(s) are specific to the dye/ nano-particle used with

marker 670 that is very specific for the desired target 671. The marker/tag is typically a protein specific antigen combined with a florescent marker. The novel probe

illumination permits delivery of intense illumination to the target for maximum system sensitivity. Many dyes excited by short (Blue/UV) wavelength light are transmitted poorly in tissue but are easily delivered by fiber 690. A second application offered for

hybrid bi-polar ablation probe 610 is for locating / destroying small cancer lesions. The probe addresses cases where surgery is not practical or it dangerous due to location or sub-operable size. Quantum-dot or dye tagged antibody materials 670 are injected into the patients where it attaches to target structure 671. Once tagged, cancer node(s) may be located, tested, and treated.

FIG. 7 Side view of auxiliary single tipped nerve probe

This probe may be used in conjunction with any of the therapeutic probes 371 and their derivatives. The needle itself will be very fine in nature, such as an acupuncture type needle. By its small size, numerous needle insertions may be accomplished with no

scarring and minimal pain. The probe 771 will be inserted in the vicinity of the target tissue through skin 330. The exposed tip of 771, 702 will be exposed and electrically connected to generator 732 via wire 734. The surface of probe 771 is covered with

dielectric 704 so the only exposed electrical contact is surface 702 and return electrode 736. Exposed tip 702 will be advanced to the vicinity of target 101 and test stimulation

current will be applied. Appropriate physiological reaction will be observed and when the tip 702 is properly located, depth will be noted via observing marks 765. External mark

755 may be applied for reference. Ablation probe 371 may then be advanced to the proximity of the target tissue under the X mark 755 and ablation/nerve destruction as described elsewhere may be performed.

5 FIG. 7A Side view of auxiliary dual-tipped nerve probe.

Dual tipped probe 772 offers an additional embodiment that eliminates return electrode pad 736. Probe frame/ handle 739 holds two fine needles, 702 and 701, in the disclosed embodiment that are spaced a short distance (a few mm) -mm apart (730). The shaft of conductive needle 701 is covered with dielectric insulator 706, similar to the construction of probe 771 (FIG. 7). The shaft of the second conductive needle 702 is covered with dielectric insulator sleeve 703. Electric generator 732 provides current to the probes via conductors 734 and 735. Current originates from 701 and returns via electrode 702. Large probe handle 739 is drawn out to teach the dual probes. To aide in probe depth measurement, markers 765 are printed on needle shafts. Dielectric insulating sleeves 703 and 706 isolate the needle shaft current from muscle layer 710. Current applied via generator 732 stimulates the nerve directly while avoiding muscle 710. Smaller probe tips with smaller current permits accurately locating small structures.

Probes 702 and 701 are very small gage needles similar in size to common acupuncture needles, thus permitting repeated probing with minimal discomfort, bleeding, and insertion force. Sharp probes are inserted thru skin 330 and muscle layer(s) 710 near nerve 101. The practitioner locates target nerve 101, then the skin surface may be marked 755 as location aide for ablation step as shown in flow chart (FIG. 5B). Once the desired site of ablation is located, ablation probe(s) 610(FIG. 6), 371 and related probes (FIG. 3), may be inserted under skin 330, illuminated 448 by tip 305. They are visible through skin (via illumination 448 from tip 305) and are guided to mark 755 (FIG. 8). The observed intensity 765 from illumination source 305 is used as an estimator of measured depth 765. This simple probe system permits rapid, accurate locating of target structures with minimal pain and injury. Accurate target location permits use of lower ablation energy thereby minimizing damage to nearby structures.

FIG. 8 Side view of guided ablation procedure with auxiliary nerve probe(s).

Auxiliary probes 771 and 772 (FIG. 7 and 7A) are used to accurately locate target structure 101. Probe 771 holds a fine conductive needle 702 that has a shaft covered with dielectric insulator 704. Electric generator 732 provides a small current to the auxiliary probe via conductor 734 and return conductor 735 via return electrode 736. The sharp auxiliary probe is inserted thru skin 330 and muscle layer(s) 710 near target nerve 101. Dielectric insulating sleeve 704 isolates needle shaft from muscle layer 710. Current is applied via generator 732 thereby stimulating the nerve directly while avoiding muscles 710. Prior art probes without insulating sleeve 704 stimulate both the nerve and muscle simultaneously, masking nerve 101 and subsequently making nerve location difficult.

Auxiliary probe 771 and 772 provide a method to quickly locate shallow or deep target structures. Shallow structures are typically marked with ink pen allowing illuminated ablation probe 371 or its equivalents to be quickly guided to mark 755. Optionally, non-illuminated probes may be used by the practitioner who simply feels for the probe tip. For deep structures, probe 771 may also be employed as an electronic beacon; small current 811 (which will be lower intensity and different from the stimulating current) from probe tip 702 is used to guide ablation probe 372. Amplifier 430 (FIG. 4) detects current from tip electrode 301 for reading and displays it by controller 401. Alternately probe 701 is used as a receiver detecting current 811 from electrode 301. Moving probe tip 301 horizontally 1202 and in depth 766 relative to auxiliary probe 702 changes current 810 inversely proportional to distance. Detected signal current 811 isolated and buffered by amplifier 430, is measured and the current is displayed to simple bar graph 554 for rapid reading. In addition, audio feedback, in which the tone is modulated by proximity of probe tip 351, 352 or equivalent in relation to auxiliary probe tip 702 is provided to minimize or eliminate the practitioner having to look away from the needle, thus assisting in accurate probe placement. Variable frequency/pitch and volume audio signal are proportional to sensed current 811 that is generated by 452. The tone signal emitted by speaker 451 (FIG. 4 and 1) provides a pleasant and accurate method to aide in probe placement. Simultaneously, illumination source 408 is modulated by amplifier 456 to blink at a rate proportional to the sensed current. This permits the practitioner to quickly and accurately guide ablation probe 372

into position using a combination of audio and visual guides. The audio and visual aides also reduce the practitioner's training/learning time. The novel real-time probe placement feedback gives the practitioner confidence that the system is working correctly so he/she can concentrate on the delicate procedure. Accurate probe location permits use of minimal energy during ablation, minimizing damage to non-target structures and reducing healing time and patient discomfort.

FIG. 9 A high-energy electro-surgery sinusoid cutting waveform 910.

Lower energy pulse width modulated (or PWM) sinusoid 920 for coagulation is also well known to electro-surgery art. Variations of cut followed by coagulation are also well known.

FIG. 10 Side view of visually guided ablation procedure.

Auxiliary probes 771 and 772 (FIG. 7 and 7A) have accurately located target structure 101 and subsequently marked target locations 140 to 144. Shallow structures are marked typically with ink pen (755) allowing illuminated ablation probe 371, 372 or equivalent to be quickly guided to that point. For deep structures, probe 771 is employed as electronic beacon, small current 811 from probe tip 702 is used to guide ablation probe 372 as taught in FIG. 8.

Ablation probe 372 is inserted thru skin 330 and muscle layer(s) 710 near nerve 101. Illumination source 408 permits practitioner to quickly and accurately guide illuminated ablation probe 372 into position. Illumination 448 from ablation probe as seen by practitioner 775 is used as an additional aide in depth estimation. Selectable nerve stimulation current 811 aids nerve 101 location within region 1204. This novel probe placement system gives practitioner confidence system is working correctly so s/he can concentrate on the delicate procedure. Accurate probe location permits use of minimal energy during ablation, minimizing damage to non-target structures and reducing healing time and patient discomfort.

Region 1203 shows the general shape of the ablation region for conical tip 301. Tip 301 is positioned in close proximity to target nerve 101. Ablation generally requires one

or a series of localized ablations. Number and ablation intensity/energy are set by the particular procedure and the desired permanence. .

Five ablation regions are illustrated **140**, **141**, **142**, **143**, and **144**; however, there could be more or less regions. Ablation starts with area **144**, then the probe is moved to **143** and so on to **140**, conversely, ablations could start at **140** and progress to **144**. Also, the practitioner could perform rotating motions, thus further increasing the areas of ablation and permanence of the procedure. Between each ablation procedure **540** (FIG. **5C**), a small nerve stimulation test current **811** is emitted from electrode **301**. The approximate effective range of the nerve stimulation current **811** is shown by **1204**.

Testing nerve response after each ablation allows the practitioner to immediately check level of nerve conduction. Without probe **372** removal, the practitioner receives immediate feedback as to the quality of the ablation. Then minor probe position adjustments are made before conducting additional ablations (if required).

FIG. 11-11A Controller and probe data base structure

Controller **101** maintains local probe **1460**, patient **1430**, and procedure **1410** databases. All work together to insure correct probes and settings are used for the desired procedure. Automatically verifying that the attached probe matches selected procedure and verifying probe authentication and usage to avoid patient cross contamination or use of unauthorized probes. Automatic probe inventory control quickly and accurately transfers procedure results to the billing system.

FIG. 11 - Procedure Parameters Code(s) Database **1410**

From a touch screen, the practitioner selects the desired procedure from list **1410**.

For example "TEMPORARY NERVE CONDUCTION" **1411**, "SMALL TUMOR ICC" **1412**, and "SMALL NERVE ABLATE" **1413** are a few of the choices. Each procedure has a unique procedure code **1416** to be used in the billing system. Power range parameter **1417** is a recommended power setting via power level control **404**. The recommended probe(s) Associated with procedure **1415** and power range parameter **1417** are listed in parameters **1419**. With the probe connected, the part number is read from

memory 331 (FIG. 1, 3 and 4) and compared to list 1419. The total power parameter 1418 is the maximum energy that the system may deliver for this procedure and is determined by the procedure code, probe being used and software parameters. These parameters may be modified, updated and changed as required by addition of new probes and procedures allowed/approved. Power is delivered, measured and totaled with integrator 435 (FIG. 4). The power integration circuit is designed as a hardwired redundant safety circuit that turns off the power amplifier if maximum energy is exceeded. This novel feature protects patients from system fault or practitioner error. Standard procedure time 1420 is doubled and added to current RTC 482 then written to probe memory 331 (in FIG. 1).

FIG. 11 & 11A - Probe Usage Authorization Database 1460

From touch screen 450 (FIG. 1 and 4) practitioner selects desired procedure from list 1410. Probe 371 and equivalents (FIG. 3A-D) type is selected from recommended list 1419 and is connected via cable 1334 (FIG. 1) to control unit 101. Once connected, controller 401 (FIG. 4) reads the stored time register from ID memory module 331 (FIG. 1). If start time 1487 read is zero (factory default), current real time clock 482 (FIG. 4) is written to database 1460 in the start time field 1467, 1430 and 1435. Simultaneously, twice the standard procedure time 1420 parameter is added to RTC 482 and written to time register 1487 via serial bus 403. If probe start time 1487 reads (331) non-zero, the value compared to real time clock 482. If greater than current time plus twice the standard selected procedure duration 1420, the controller alerts the practitioner via display 450, speaker 451 and flashing probe illumination 608 of previously probe used condition. To correct the situation, the practitioner simply connects a new sterile probe and repeats the above process. Figure 13 teaches additional detail regarding probe verification usage and related database operations. Periodically controller 401 performs the above verification to alert practitioner that he/she has forgotten to change probe(s).

During the procedure (FIG. 10), various parameters such as peak temperature 1473, power 1472, impedance, etc... are read, scaled, stored and displayed. Parameters such as procedure start 1467; end time 1468, serial number 1469, and part number 1468 are recorded as well. Critical parameters are written to local high-speed memory 438 for

display and analysis. On a time permitting or end of procedure, data is mirrored to removable USB 1320 memory stick 1338. Probe specific parameters 1463 are copied and written to probe memory 1338 for use at probe refurbishment facility. Database checksum/CRC(s) 1449, 1479, and 1499 are check and updated as required. Faults such as shorts (dielectric 305 (FIG. 3) breakdown) that are detected are saved to error field 1494 and 1474. If network connection 1305 is available, email request for replacement probe are automatically sent to repair/customer service center 1308. Defective probe 374 with saved failure information 1494 is returned for credit and repair.

Use of a USB memory stick permits continued operation in the event of a network 1326 failure. Data is loaded to memory 1338 for simple transfer to office computer 1306 (FIG. 1) for backup. Commonly available USB memory sticks 1320 have large data capacities in the tens to hundreds of megabytes at a low cost with long retention times. USB memory sticks also can support data encryption for secure transfer of patient data. Sealed versions are available as well compatible with chemical sterilization procedures.

If computer network 1326 such as Ethernet 802.11 or wireless 802.11x is available, files are mirrored to local storage 1309, remote server 1307. The remote server (typically maintained by equipment manufacture) can be remotely update procedure(s). To insure data integrity and system reliability a high availability database engine made by Birdstep of Americas Birdstep technology, Inc 2101 Fourth Ave. Suite 2000, Seattle Washington is offered as an example. The Birdstep database supports distributed backups, extensive fault and error recovery while requiring minimal system resources.

FIG. 11 – Patient/Procedure Database 1430

From a touch screen, the practitioner selects or enters patient name from previous procedure 1430 and creates a new record 1433. Similarly, a procedure is selected from 1410 (for example “TEMPORARY NERVE CONDUCTION” 1411, “SMALL TUMOR 1CC” 1412, and “SMALL NERVE ABLATE” 1413). Each procedure has a unique procedure code 1416 that is used for the billing system. Other information such as practitioners name 1440, date 1435 is entered to record 1433. As taught above probe

appropriate for the procedure is connected and verified, part **1470** and serial number **1469** recorded.

FIG. 11 – Voice and Notes

The practitioner enters additional text notes to file **1442** or records them with
5 microphone **455** (**FIG. 5**) to wave file **1445** for later playback or transcription. The
instant invention permits temporary / permanent nerve conduction interruption. Thus,
procedures are performed at intervals from months to years apart. A hands free
integrated voice recorder is extremely useful. Detailed text and voice notes made while
probing/ablating are also recording specific settings, and patient response. A feature that
10 is very helpful when reviewing treatment progress and saves valuable time instead of
writing notes. Practitioners play back voice/wave files **1445** with standard audio tools a
his/or hers desk. Audio files **1445** can be sent via email or file transfer for transcription,
updating note field **1442**.

At the end of procedure, records are updated and stored to memory **438**. Backup
15 copies are written to USB **1320** memory stick **1338** (**FIG. 1**). If computer network **1326**
such as Ethernet 802.11 or wireless 802.11x is available, files are mirrored to local
storage **1309**, remote server **1307**. Patient name **1436**, procedure date **1435**, and
procedure codes **1416** are automatically transferred via network or USB device **1320** to
billing system **1306**. USB memory stick permits continued operation in the event of a
20 network **1326** failure. Data is loaded to USB memory **1338** for simple transfer to office
computer **1306** (**FIG. 1**) for backup. USB memory sticks **1320** have large data
capacities in the tens to hundreds of megabytes at a low cost with long retention times.
USB memory stick also support data encryption for secure transfer of patient data.
Insuring patient is accurately billed with minimal office paper work. Probe inventory is
25 automatic maintained with replacement probes automatic shipped as needed.

We claim :

- 1) A System for Minimally Invasive Surgery comprising:
 - a. an electrically isolated RF Energy Generator, that delivers up to 500 watts of RF energy in amplitude or frequency modulated form with a frequency between 50Khz and 2.5Mhz;
 - b. a single-needle bi- or multi- polar probe that requires but a single puncture entranceway and has electrodes in close proximity to the extent necessary to promote precision within the procedure itself; and
 - c. a secondary means to locate and position said single-needle probe by illumination, the creation of electrical signal or signals, or by use of florescent dye.
- 2) A generator as described in claim #1 that delivers RF energy regulate-able intelligently by use of dynamic load detection measuring the effective load by voltage, current, phase or varying frequency comprising:
 - a. connection to the probe;
 - b. connection to the probe's internal microcontroller for memory and sensor reading and writing if any, and to retrieve procedural, control sequence and limitations that are in turn used for that probe's specific procedure;
 - c. display and sound as required for surgical functionality;
 - d. memory storage for record keeping of procedural information related to the operating parameters, date, time, sensor measurements taken, and voice or data recording; and
 - e. connection to a communication channel such as RS-232, RS-485, Ethernet, Bluetooth, or any other viable communication media.
- 3) A single needle two electrode probe used in a bi- or multi- polar configuration for Minimally Invasive Surgery comprising:
 - a. an inner diameter electrode made of surgical grade metal of a size and shape dictated by the application requirement;
 - b. a voltage insulator that covers and creates an electrical isolation between the two exposed electrodes; and
 - c. an Outer-sleeve return-electrode made of a surgical grade metal with surface area greater than that necessary to eliminate burning of the tissue in contact;
- 4) A single needle multiple electrode probe used in a multi-polar configuration for Minimally Invasive Surgery comprising:
 - a. an inner diameter electrode made of surgical grade metal of a size and shape dictated by the application requirement;
 - b. a voltage insulator that covers and creates an electrical isolation between the two exposed electrodes; and
 - c. an Outer-sleeve return-electrode made of a surgical grade metal with surface area greater than that necessary to eliminate burning of the tissue in contact;
- 5) A single needle probe as in claim #3 or #4 with a inner diameter electrode hollow such that injections of medications, florescent dyes and the like can be made and samples of the surrounding tissue can be taken.

- 6) A single needle probe as in claims #3, #4, or #5 that communicates, to the generator, information related to the procedure, measurements of sensors embedded within the probe and probe specific information.
- 7) A single needle probe as in claim #3, #4, #5 or #6 with an electrical isolator that is capable of illuminating the area so that placement of the probe can be facilitated;
- 8) A method for ablating tissues or terminating the flow of nerve impulses utilizing a single puncture probe introduced via a Minimally Invasive surgical techniques comprising:
 - a. locating probe tip in close proximity to said nerve or target tissue with a needle type probe having an exposed active area or areas on or near the distal tip, said probe and system to generate RF energy so as to ablate, destroy tissue or render nerve conduction through said nerves impossible on either semi permanent or permanent basis;
 - b. placing said probe tip in position so that ablative energy may be selectively delivered to target tissue thus avoiding destruction or areas and tissues that must remain intact and not be destroyed or traumatized; and
 - c. delivering RF energy from a tuned RF source so as to destroy target tissues in close proximity to electrode(s) at tip.
- 9) A method as in claim #7 wherein guidance between auxiliary probes and ablation probes is provided via current signals, illumination or other means.
- 10) A method as in claim #7 wherein positioning involves placing tip of the probe in desired general area using physiologic and anatomic landmarks with manual guidance.
- 11) A method as in claim #7 wherein precise positioning is done using illumination from tip region of probe so operator can see exact location of tip through the skin and other intervening structures.
- 12) A method as in claim #7 whereby the therapeutic probe is guided in to general area desired and then directed precisely under surface marking by observing the location of illumination point emanating from tip of probe.
- 13) A method as in claim #7 wherein auxiliary probes are inserted into vicinity of target tissues, stimulation energy is applied from the auxiliary probes, location is determined, and the target area is identified by marking the tissue or other means.
- 14) A method as in claim #7 wherein nerve, muscle, or physiologic reaction is observed by applying stimulation currents from ablative tip(s), thus confirming proper location of tip in relation to target tissue(s).