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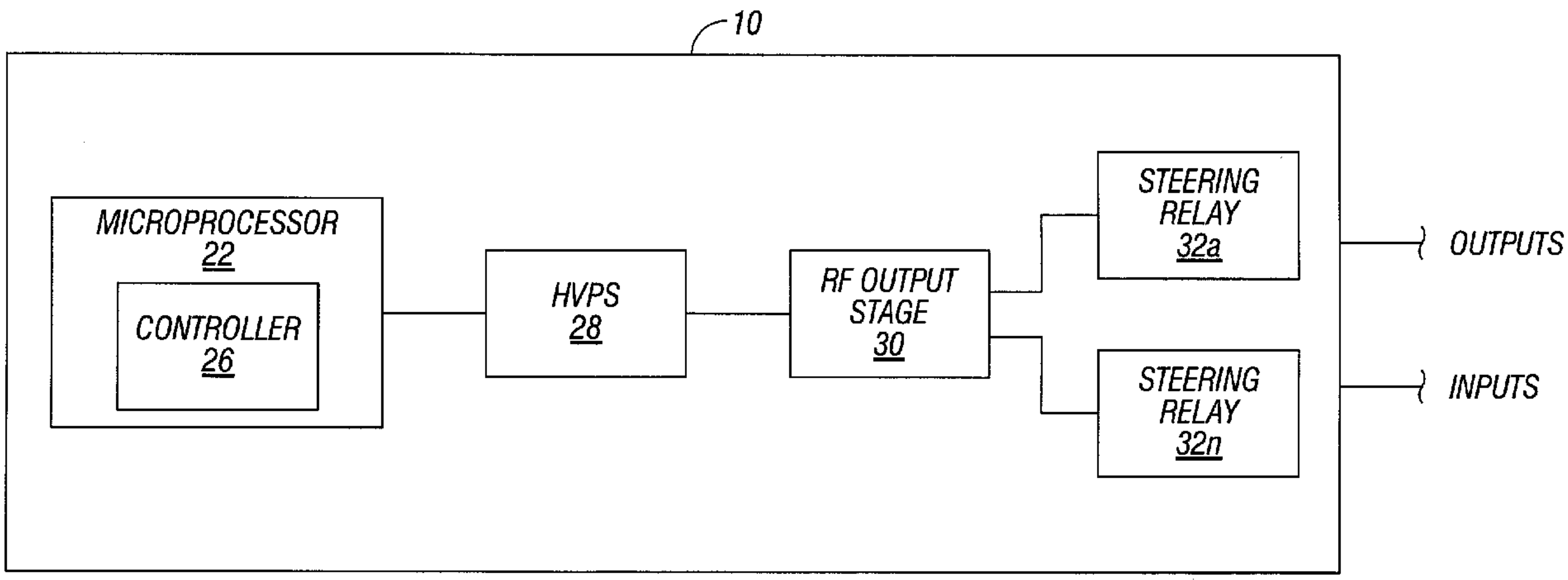
(54) **Titre :** SYSTEME ET METHODE DE MONITORAGE EN BOUCLE FERMEE D'UN APPAREIL D'ELECTROCHIRURGIE MONOPOLAIRE

(54) **Title:** SYSTEM AND METHOD FOR CLOSED LOOP MONITORING OF MONOPOLAR ELECTROSURGICAL APPARATUS



(57) **Abrégé/Abstract:**
An electrosurgical system is disclosed comprising a generator configured to electrosurgical coagulation waveforms. The generator includes a closed loop control system for controlling the electrosurgical coagulation waveforms. The closed loop control system includes a sensor configured to sense a tissue property and/or an energy property and to transmit the tissue property and/or the energy property as one or more sensor signals having an amplitude. The control system also includes a gain controller configured to process the at least one sensor signal to reduce the amplitude of the sensor signals and to obtain a signal to noise ratio of the at sensor signals within a predetermine range. A microprocessor coupled to the generator and is configured to adjust the electrosurgical coagulation waveforms as a function of the sensor signals.

ABSTRACT

An electrosurgical system is disclosed comprising a generator configured to electrosurgical coagulation waveforms. The generator includes a closed loop control system for controlling the electrosurgical coagulation waveforms. The closed loop control system includes a sensor configured to sense a tissue property and/or an energy property and to transmit the tissue property and/or the energy property as one or more sensor signals having an amplitude. The control system also includes a gain controller configured to process the at least one sensor signal to reduce the amplitude of the sensor signals and to obtain a signal to noise ratio of the at sensor signals within a predetermine range. A microprocessor coupled to the generator and is configured to adjust the electrosurgical coagulation waveforms as a function of the sensor signals.

SYSTEM AND METHOD FOR CLOSED LOOP MONITORING OF MONOPOLAR ELECTROSURGICAL APPARATUS

BACKGROUND

1. Field

The present disclosure relates generally to electrosurgical system and method, more specifically, to a system and method for closed loop monitoring of monopolar electrosurgical apparatus to sense tissue and energy properties and control energy delivery based on the sensed properties.

2. Description of the Related Art

Electrosurgery involves application of high radio frequency electrical current to a surgical site to cut, ablate, or coagulate tissue. In monopolar electrosurgery, a source or active electrode delivers radio frequency energy from the electrosurgical generator to the tissue and a return electrode carries the current back to the generator. In monopolar electrosurgery, the source electrode is typically part of the surgical instrument held by the surgeon and applied to the tissue to be treated. A patient return electrode is placed remotely from the active electrode to carry the current back to the generator.

In bipolar electrosurgery, one of the electrodes of the hand-held instrument functions as the active electrode and the other as the return electrode. The return electrode is placed in close proximity to the active (current supplying) electrode such that an electrical circuit is formed between the two electrodes. Commonly, electrodes in bipolar electrosurgical systems are disposed within electrosurgical forceps, which lend itself particularly well to vessel sealing. In this manner, the applied electrical current is limited to the body tissue positioned between the electrodes. When the electrodes are sufficiently separated from one another, the electrical circuit is open and thus inadvertent contact of body tissue with either of the separated electrodes does not cause current to flow.

Electrosurgical generators are capable of producing a variety of electrical waveforms. Certain waveforms are better suited for specific electrosurgical procedures. A continuous waveform having a duty cycle of 100% is best suited for cutting the tissue since the energy produces heat very rapidly thereby vaporizing the tissue. An intermittent waveform, where the duty cycle of about 10% is best suited for coagulating the tissue since the amount of heat generated is reduced.

Currently parameters affecting the coagulation waveform are adjusted manually by the surgeon. This adjustment process is cumbersome since the coagulation waveform may need to be adjusted continuously during its delivery. However, there are no systems available which can adjust the coagulation waveform automatically.

SUMMARY

The present disclosure provides for an electrosurgical system having closed loop monitoring. The system includes an electrosurgical generator having an RF output stage for generating electrosurgical waveforms suitable for coagulation and a microprocessor for controlling the RF output stage. The closed loop monitoring includes a sensor for sensing one or more tissue properties, such as voltage, current, temperature. The sensor transmits data pertaining to the tissue properties to the microprocessor which adjusts generator output. More specifically, the generator adjusts the electrosurgical waveforms in response to the data to correspond with predetermined waveform parameters.

An electrosurgical system is also disclosed, which is configured to provide automatic closed loop control of the RF energy in direct response to tissue changes until a desired clinical hemostasis effect is achieved. The system includes a generator having a high speed high voltage power source ("HVPS") for supplying direct current ("DC") output. The HVPS is configured to adjust DC output in a rapid and dynamic fashion. The generator includes an RF output stage which is configured to generate radio frequency ("RF") energy comprising one or more electrosurgical coagulation waveforms suitable for coagulating tissue. The system also includes an RF sensor for sensing properties of the RF energy and generating an RF signal indicative of the RF energy. The sampling rates for sensing are sufficient to allow the generator to sculpt the electrosurgical coagulation waveforms in real time as a function of the RF sensor signal in order to match the waveforms to the RF stage. The system further includes a closed loop control system which controls the electrosurgical coagulation waveform. Additionally, the system includes one or more gain controllers configured to amplify the RF sensor signal to maintain a predetermined signal to noise ratio and to provide RF voltage and current correction of the RF sensor signal which is then transmitted to the controller to allow for real time modification of RF energy.

According to one aspect of the present disclosure an electrosurgical system is disclosed which includes a generator configured to generate electrosurgical coagulation waveforms. The generator includes a closed loop control system which controls the electrosurgical coagulation waveforms. The closed loop control system includes a sensor configured to sense a tissue property or an energy property and transmit the tissue property or an energy property as one or more sensor signals having an amplitude. The control system also includes a gain controller configured to process the sensor signals to reduce the amplitude thereof and to obtain a signal to noise ratio of the sensor signals within a predetermine range. Microprocessor is coupled to the generator and is configured to adjust the electrosurgical coagulation waveforms as a function of the sensor signals.

According to another aspect of the present disclosure a closed loop control system for controlling electrosurgical coagulation waveforms is disclosed. The closed loop control system includes a sensor configured to sense a tissue property or an energy property and transmit the tissue property or energy property as one or more sensor signals having an amplitude. The control system also includes a gain controller configured to process the sensor signals to reduce the amplitude thereof and to obtain a signal to noise ratio of the sensor signals within a predetermine range. Microprocessor is coupled to the generator and is configured to adjust the electrosurgical coagulation waveforms as a function of the sensor signals.

A method for controlling electrosurgical coagulation waveforms is also contemplated by the present disclosure. The method includes the steps of sensing a tissue property or an energy property and transmitting the tissue property or an energy property as sensor signals having an amplitude and processing the sensor signals to reduce the amplitude thereof and to obtain a signal to noise ratio of the sensor signals within a predetermine range. The method also includes the step of adjusting the electrosurgical coagulation waveforms as a function of the sensor signals.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and other aspects, features, and advantages of the present disclosure will become more apparent in light of the following detailed description when taken in conjunction with the accompanying drawings in which:

Fig. 1 is a schematic block diagram of an electrosurgical system;

Fig. 2 is a schematic block diagram of a generator according to the present disclosure; and

Figs. 3A-B are a schematic block diagrams of closed loop coagulation control according to the present disclosure.

DETAILED DESCRIPTION

Particular embodiments of the present disclosure will be described herein below with reference to the accompanying drawings. In the following description, well-known functions or constructions are not described in detail to avoid obscuring the present disclosure in unnecessary detail.

The present disclosure provides for an electrosurgical system having precision closed loop monitoring of tissue and energy properties. The system includes a generator which is configured for high-speed power sourcing of radio frequency (RF) energy. The control loop includes a plurality of sensors for sensing tissue and energy properties and gain control for modifying generator output. The sensors monitor tissue properties in real time to allow an embedded controller to provide corrective adjustment to the delivered RF energy. The closed control loop automatically corrects the applied RF energy, based on tissue and energy properties according to prescribed algorithm determined by the clinical procedure. The generator receives the corrective adjustment from the controller and dynamically modifies the delivered energy in direct response to changes in tissue properties until a desired clinical effect is achieved.

Fig. 1 is a schematic illustration of an electrosurgical system 1 configured for a monopolar procedure. The system 1 includes an active electrode 14 and a return electrode 16 for treating tissue of a patient P. Electrosurgical RF energy is supplied to the active electrode 14 by a generator 10 via a cable 18 allowing the active electrode 14 to ablate, cut or coagulate the tissue. The return electrode 16 is placed at the patient P to return the energy from the patient P to the generator 10 via a cable 19.

The generator 10 includes input controls (e.g., buttons, activators, switches, etc.) for controlling the generator 10. The controls allow the surgeon to adjust power of the RF energy, waveform, and other parameters to achieve the desired waveform suitable for a particular task (e.g., cutting, coagulating, etc.). Disposed between the generator 10 and the active electrode 14 on the cable 18 is a hand piece 12, which includes a plurality of input controls which may be redundant with certain input controls of the generator 10. Placing the input controls at the hand piece 12 allows for easier and faster modification of RF energy parameters during the surgical procedure without returning to the generator 10. It is also envisioned that a footswitch may be connected to the generator 10 to control energy delivery during monopolar procedures. It is further envisioned that the hand piece 12 and the electrode 14 can be incorporated into a single instrument e.g., a surgical pencil, with the electrode 14 being disposed at a distal end of the hand piece 12.

Fig. 2 shows a schematic block diagram of the generator 10 having a microprocessor 22, a high voltage DC power supply ("HVPS") 28, an RF output stage 30, at least one RF sensor 32 configured to measure one or more tissue and/or energy properties, and a gain controller 34. The microprocessor 22 includes a controller 26 and an output port which is electrically connected to the HVPS 28 configured to supply DC voltage, from about 0 V to about 200 V, to the RF output stage 30. The microprocessor 22 receives input signals from the generator 10, the hand piece 12, or the footswitch and the controller 26, in turn, adjusts output parameters of the generator 10, more specifically the HVPS 28, and/or performs other control functions thereon. It is also envisioned that the controller 26 is configured to receive control signals from the gain controller 34 for dynamic adjustment to the RF energy being delivered to the tissue.

The RF output stage 30 converts DC power into RF energy and delivers the RF energy, at about 470 KHz, to the active electrode 14 or other electrosurgical devices connected to the generator 10. In addition, the RF output stage 30 also receives RF energy from the return electrode 16. The RF sensor 32 is connected to the input and output (e.g., the connections to the active electrode 14 and the return electrode 16) of the RF output stage 30 to sense tissue and energy properties (e.g., impedance, voltage, current, temperature, phase, voltage peak, crest factor, current peak, real and reactive power, voltage rate change over time [dv/dt], phase rate change over time [dϕ/dt], current rate change over time [dI/dt], temperature rate change over time [dT/dt], impedance rate change over time [dz/dt], high order harmonics of the fundamental 472 kHz waveform, etc.)

The generator 10 includes a closed loop control system 50 having the microprocessor 22, the controller 26, the RF sensor 32 and the gain controller 34 along with components thereof shown in Figs. 3A-B and discussed in more detail below. The RF sensor 32 transmits signals representing tissue and/or energy properties through the gain control 34 to adjust the RF energy output accordingly. Sensed properties are transmitted to the microprocessor 22 and the controller 26 to perform calculations to determine the adjustments which have to be made to the RF energy output. The microprocessor 22 compares impedance, voltage, and other measurements to desired values and signals the RF output stage 30 to make any adjustments necessary to achieve the desired values.

In addition to impedance and voltage, the microprocessor 22 also measures voltage at a peak of the waveform (Vpk) and root-mean-square voltage (Vrms). Peak and rms calculations are also performed using current (I) value. To calculate rms values, the sample rates of the voltage and current signals must correspond to the buffer size of the sensor 32. More specifically, the microprocessor 22 includes a buffer which is sized so that it contains an integer number of full cycles of the waveform at a specified sample rate to avoid modulation errors within the rms values. This allows the sensor 32 to tailor the data acquisition to the varied waveforms associated with coagulation RF energy.

The microprocessor 22 calculates crest factor (Vpk/Vrms or Ipk/Irms) and V and I peak values in real time and controls output waveform timing and RF amplitude as a function thereof. It is envisioned that real time calculation of crest factor can be used to adjust the RF energy or adjust the waveform to keep a crest factor profile. More specifically, real time calculation of crest factor allows for coagulation modes to be controlled by adjusting the output RF energy to maintain a predetermined crest factor. Either crest factor or V and I peak values can be held constant and adjust the output waveform timing and RF amplitude accordingly.

The gain controller 34 processes sensed voltage and current signals received from the RF sensor 32. More specifically, the gain controller 34 reduces high amplitudes of coagulation voltage and current signals which allows for the signals to be transmitted into the microprocessor 22 for processing. The gain control 34 provides for both amplification and attenuation of the voltage and current signals to obtain good signal to noise ratios to minimize bit quantization error. Resolution and accuracy of the sensed RF delivered to precisely control the patient energy dosage.

With reference to Figs. 3A-B, the gain control process is illustrated in two embodiments. Fig 3A, shows the gain controller 34 which includes RF sensor voltage scaler control 35 and a gain control 37 connected to an analog multiplier 36 which is then connected to an anti-alias filter 38. In this embodiment, the gain controller 34 adjusts the sensed voltage of the RF energy. The voltage scaler 35 which receives RF signals (e.g., signals representative of the RF energy being outputted by the generator 10) from the RF sensor 32 and dynamically and automatically scales the RF signal to adjust the high amplitude levels of the RF coagulation voltage and current signals. The gain control 37 provides real time gain modification of the RF energy by processing a variable DC level control signal received from the controller 26. The analog multiplier 36 performs a real time multiplication of signal inputs received from the outputs of the voltage scaler 35 and the gain control 37. The analog multiplier 36 normalizes the RF sensor signals independent of the high amplitude levels of the RF output 30 to maximize the precision of the delivered RF energy.

The anti-alias filter 38 blocks the fundamental RF frequency and harmonics from contributing errors to the computed processing performed by the controller 26. The filter 38 processes the RF energy to reduce RF noise components and increase the accuracy of the delivered RF energy to the patient. It is also envisioned that the RF sensor 32 also includes an amplitude reduction circuit (not shown) to protect the front end of the multiplier 44.

Fig. 3B shows another embodiment of the gain controller 34 which includes an RF sensor current scaler control 39. In this embodiment, the gain controller 34 adjusts the sensed current of the RF energy. Gain control 37 is connected to the analog multiplier 36 and anti-alias components in similar manner as shown in Fig. 3A and discussed above. The output from the anti-alias filter 38 is fed to the output line (e.g., leading to the controller 26). In Fig. 3B, the output of the analog multiplier 36 is current mapped 1:1 to the RF sensor current input received from the RF sensor 32. Summer 40 processes the difference signals between the analog multiplier 36 and the RF sensor current input in conjunction with an operational amplifier ("OP amp") 44 to create an equivalent normalized RF output signal independent of the high amplitude levels of the RF output stage 30. Input limiter 42 provides surge protection to the OP amp 44 input, to increase the reliability of the gain controller 34.

The generator 10 is capable of making small adjustments to the RF waveform of high resolution (e.g., 10 ns). This allows control of crest factor and peak outputs as well as tuning of the output waveforms so that the output frequency can be adjusted to match the resonant frequency of the RF output stage 30. The generator 10 is configured to sculpt output curves to a degree using a linear interpolation method which allows any curve described within a predetermined number of points (e.g., 15), where the curves represent either current, power, voltage etc.

The scope of the claims should not be limited by the preferred embodiments set forth herein, but should be given the broadest interpretation consistent with the description as a whole.

The embodiments of the present invention for which an exclusive property or privilege is claimed are defined as follows:

1. An electrosurgical system comprising:

a generator configured to generate at least one electrosurgical coagulation waveform, the generator includes a closed loop control system that controls the at least one electrosurgical coagulation waveform, the closed loop control system including:

a sensor configured to sense at least one of a tissue property and an energy property and transmit the at least one of a tissue property and an energy property to a gain controller as a voltage sensor signal having an amplitude;

the gain controller configured to process the voltage sensor signal to reduce the amplitude of the voltage sensor signal and obtain a signal to noise ratio of the voltage sensor signal within a predetermined range;

the gain controller being a voltage gain controller that includes:

a sensor voltage scaler control configured to scale the amplitude of the voltage sensor signal and to generate a scaled sensor signal;

a gain control configured to process a variable DC level control signal to generate a gain control signal; and

a multiplier coupled to the sensor voltage and the gain control, the multiplier configured to multiply in real-time the scaled sensor signal and the gain control signal to normalize the voltage sensor signal independent of the amplitude thereof; and

a microprocessor coupled to the generator and configured to adjust the at least one electrosurgical coagulation waveform as a function of the voltage sensor signal.

2. The electrosurgical system according to claim 1, wherein the voltage gain controller includes:

an anti-alias filter configured to substantially block a harmonic radio frequency.

3. An electrosurgical system comprising:

a generator configured to generate at least one electrosurgical coagulation waveform, the generator includes a closed loop control system which controls the at least one electrosurgical coagulation waveform, the closed loop control system including:

a sensor configured to sense at least one of a tissue property and an energy property and transmit the at least one of a tissue property and an energy property to a gain controller as a current sensor signal having an amplitude;

the gain controller configured to process the current sensor signal to reduce the amplitude of the current sensor signal and obtain a signal to noise ratio of the current sensor signal within a predetermined range;

the gain controller being a current gain controller that includes:

a sensor current scaler control configured to scale the amplitude of the current sensor signal and to generate a scaled sensor signal;

a gain control configured to process a variable DC level control signal to generate a gain control signal;

a multiplier configured to generate a multiplied signal in real-time as a function of the scaled sensor signal and the gain control signal;

a summer configured to generate a difference signal as a function of the multiplied signal and the current sensor signal; and an operational amplifier configured to amplify the difference signal to normalize the current sensor signal independent of the amplitude thereof; and

a microprocessor coupled to the generator and configured to adjust the at least one electrosurgical coagulation waveform as a function of the current sensor signal.

4. The electrosurgical system according to claim 3, wherein the current gain controller includes:

an input limiter to provide surge protection for the operational amplifier.

5. The electrosurgical system according to claim 3, wherein the current gain controller includes:

an anti-alias filter configured to substantially block a harmonic radio frequency.

6. The electrosurgical system according to claim 1, wherein the microprocessor includes a buffer sized to store an integer multiple of a repetition rate of the voltage sensor signal.

7. The electrosurgical system according to claim 1, wherein the microprocessor is configured to calculate at least one of a RMS value, a peak value, and crest factor of the voltage sensor signal and adjust the at least one electrosurgical coagulation waveform as a function thereof.

8. A closed loop control system for controlling at least one electrosurgical coagulation waveform, the closed loop control system including:

a sensor configured to sense at least one of a tissue property and an energy property and transmit the at least one of a tissue property and an energy property to a gain controller as a voltage sensor signal having an amplitude;

the gain controller configured to process the voltage sensor signal to reduce the amplitude of the sensor signal and to obtain a signal to noise ratio of the voltage sensor signal within a predetermined range;

the gain controller being a voltage gain controller that includes:

a sensor voltage scaler control configured to scale the amplitude of the voltage sensor signal and to generate a scaled sensor signal;

a gain controller configured to process a variable DC level control signal to generate a gain control signal; and

a multiplier coupled to the sensor voltage scaler and the gain control, the multiplier configured to multiply in real-time the scaled sensor signal and the gain control signal to normalize the voltage sensor signal independent of the amplitude thereof; and

a microprocessor coupled to the generator configured to adjust the at least one electrosurgical coagulation waveform as a function of the voltage sensor signal.

9. The closed loop control system according to claim 8, wherein the voltage gain controller includes:

an anti-alias filter configured to substantially block a harmonic radio frequency.

10. A closed loop control system for controlling at least one electrosurgical coagulation waveform, the closed loop control system including:

a sensor configured to sense at least one of a tissue property and an energy property and transmit the at least one of a tissue property and an energy property to a gain controller as a current sensor signal having an amplitude;

the gain controller configured to process the sensor signal to reduce the amplitude of the current sensor signal and to obtain a signal to noise ratio of the current sensor signal within a predetermined range;

the gain controller being a current gain controller that includes:

a sensor current scaler control configured to scale the amplitude of the current sensor signal and to generate a scaled sensor signal;

a gain control configured to process a variable DC level control signal to generate a gain control signal;

a multiplier configured to generate a multiplied signal in real-time as a function of the scaled sensor signal and the gain control signal;

a summer configured to generate a difference signal as a function of the multiplied signal and the current sensor signal; and

an operational amplifier configured to amplify the difference signal to normalize the current sensor signal independent of the amplitude thereof; and

a microprocessor coupled to the generator configured to adjust the at least one electrosurgical coagulation waveform as a function of the current sensor signal.

11. The closed loop control system according to claim 10, wherein the current gain controller includes:

an input limiter to provide surge protection for operational amplifier.

12. The electrosurgical system according to claim 11, wherein the current gain controller includes:

an anti-alias filter configured to substantially block a harmonic radio frequency.

13. The electrosurgical system according to claim 3, wherein the microprocessor includes a buffer sized to store an integer multiple of a repetition rate of the current sensor signal.

14. The electrosurgical system according to claim 3, wherein the microprocessor is configured to calculate at least one of a RMS value, a peak value, and crest factor of the current sensor signal and adjust the at least one electrosurgical coagulation waveform as a function thereof.

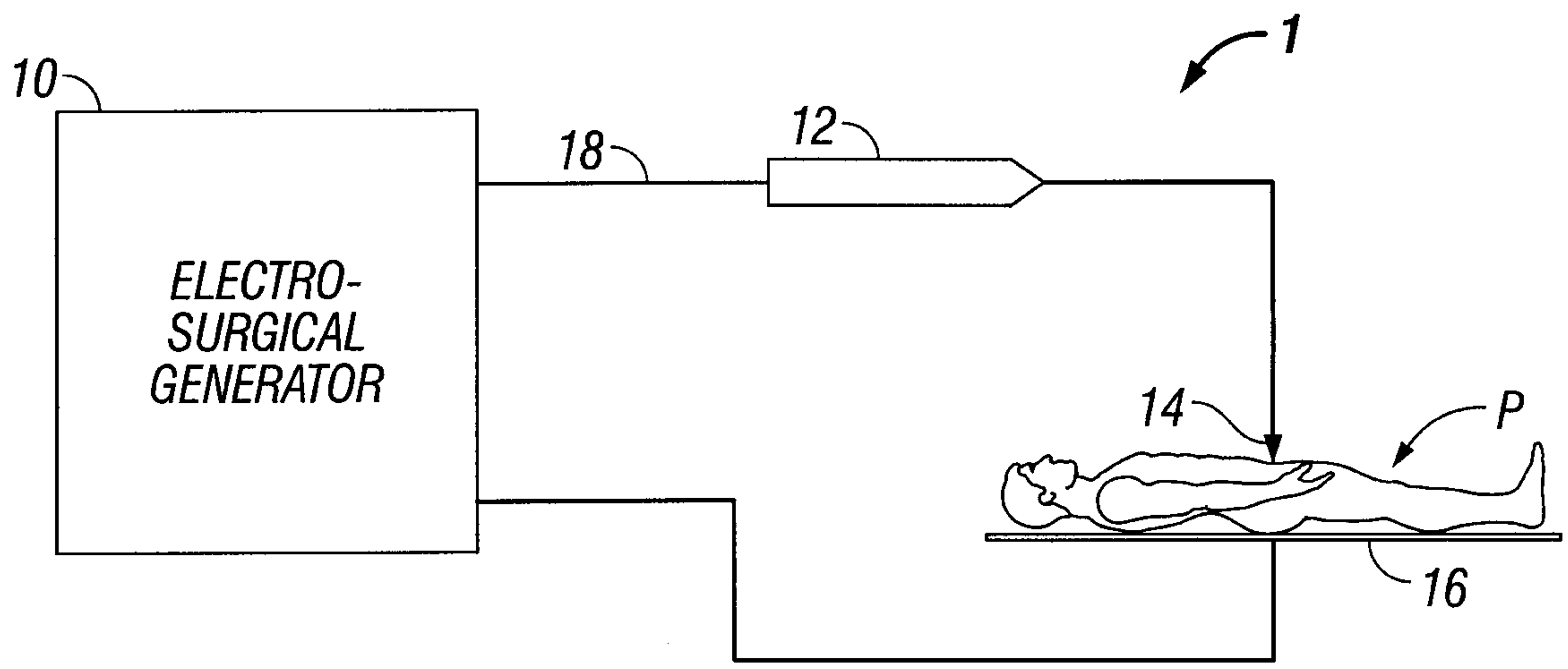


FIG. 1A

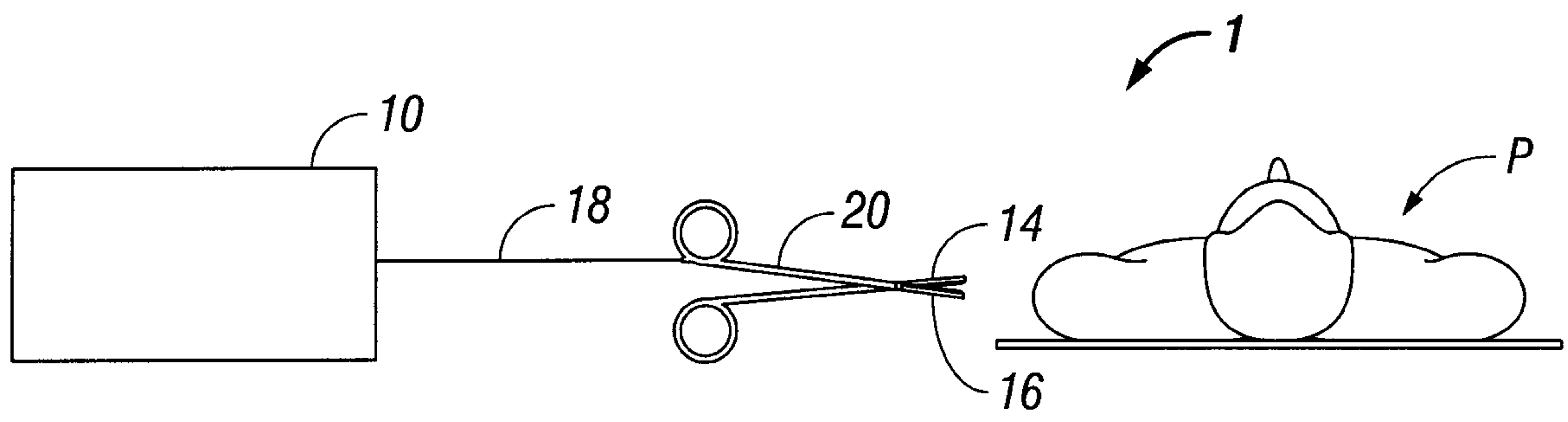
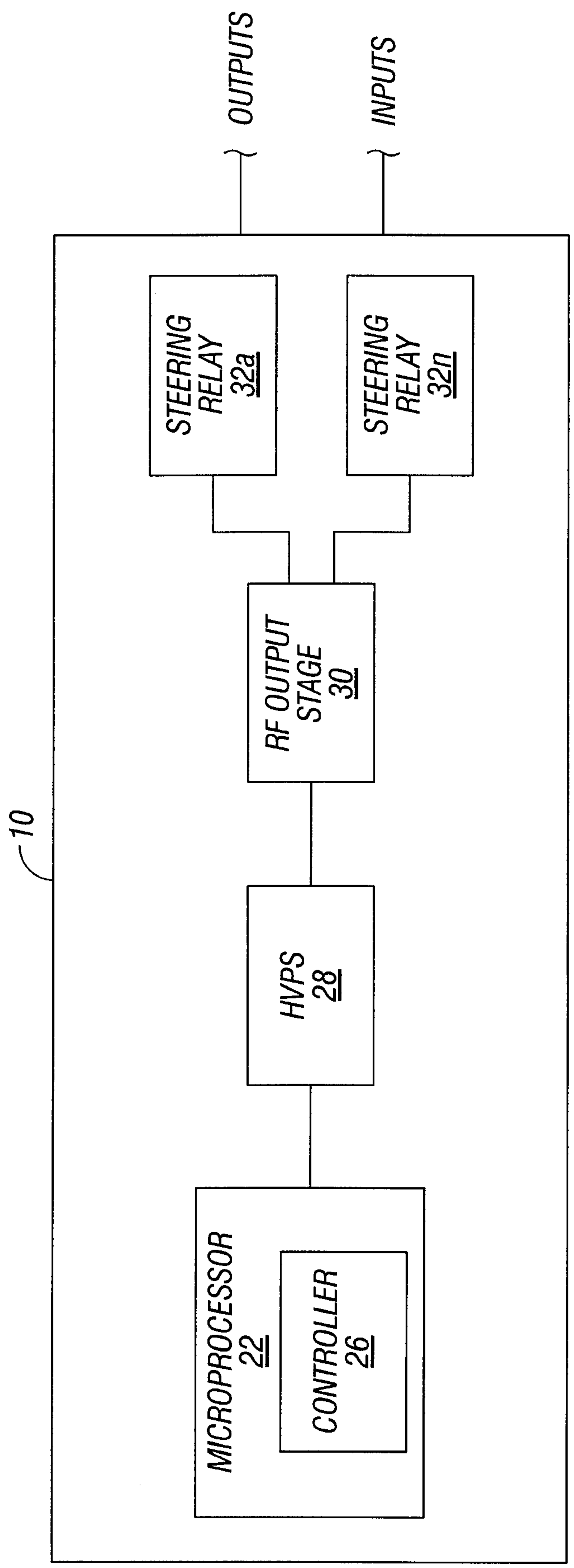


FIG. 1B



OUTPUTS
INPUTS
10
STEERING RELAY 32a
STEERING RELAY 32n
RF OUTPUT STAGE 30
HVPS 28
MICROPROCESSOR 22
CONTROLLER 26

FIG. 2

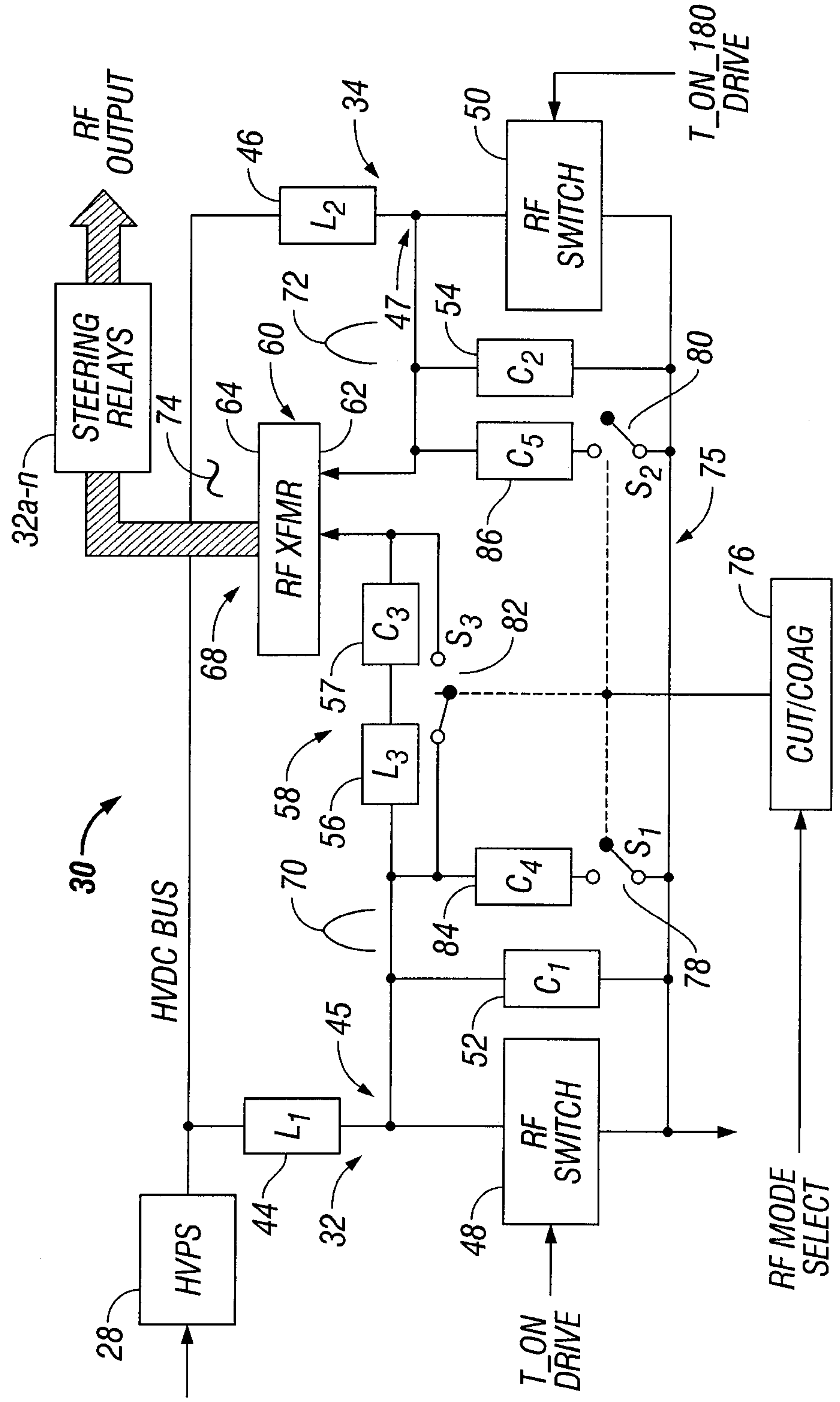

RF OUTPUT
STEERING RELAYS
32a-n
74
HVDC BUS
30
HVPS
28
L_1
44
32
45
L_2
46
34
47
72
RF XFMR
60
64
62
68
C_3
57
S_3
82
L_3
56
58
70
C_4
84
C_1
52
C_2
54
C_5
86
S_2
80
75
S_1
78
RF SWITCH
48
T_ON DRIVE
RF SWITCH
50
T_ON_180 DRIVE
CUT/COAG
76
RF MODE SELECT

FIG. 3


10
MICROPROCESSOR
22
CONTROLLER
26
HVPS
28
RF OUTPUT
STAGE
30
STEERING
RELAY
32a
STEERING
RELAY
32n
OUTPUTS
INPUTS