ELECTROSURGICAL GENERATOR AND METHOD FOR CROSS-CHECKING MODE FUNCTIONALITY

The functionality and the mode of operation are evaluated in an electrosurgical generator by determining whether a patterned pulse signal that contributes to the generation of electrosurgical energy is as expected. A number of pulses in the patterned pulse signal is compared to an expected number of pulses, and an error condition is indicated when the two values are not the same or differ by more than a predetermined amount. The expected number of pulses depends on a mode of operation of the electrosurgical generator. The error condition may be used to as a basis to terminate the output power delivery.
ELECTROSURGICAL GENERATOR AND METHOD FOR CROSS-CHECKING MODE FUNCTIONALITY

Field of the Invention

This invention generally relates to electrosurgery. More specifically, the invention relates to a new and improved electrosurgical generator and method that checks the mode of operation of the electrosurgical generator to assure proper functionality of the electrosurgical generator and that the desired electrosurgical clinical effect is delivered during the surgical procedure.

Background of the Invention

Electrosurgery involves applying relatively high voltage, radio frequency (RF) electrical power to tissue of a patient undergoing surgery, for the purpose of cutting the tissue, coagulating or stopping blood or fluid flow from the tissue, or cutting or coagulating the tissue simultaneously. The high voltage, RF electrical power is created by an electrosurgical generator, and the electrical power from the generator is applied to the tissue from an active electrode manipulated by a surgeon during the surgical procedure.

The amount and characteristics of the electrosurgical energy delivered to the patient is determined by the surgeon and depends on the type of procedure, among other things. For example, cutting is achieved by delivering a continuous RF signal ranging up to relatively high power, for example 300 watts. Coagulation is achieved by rapidly switching the RF power on and off in a duty cycle. The coagulation duty cycle has a frequency considerably lower than the RF power delivered. However, during the on-time of each duty cycle, the electrical power is delivered at the RF frequency. The power delivered during coagulation is typically in the neighborhood of approximately 40-80 watts, although power delivery as low as 10 watts or as high as 110 watts may be required. Simultaneous cutting and coagulation, which is also known as a "blend" mode of operation, also involves a duty cycle delivery of RF energy, but the on-time of the duty cycle during blend is greater than the on-time of the duty cycle during coagulation. Power is delivered at the RF frequency because the frequency is high enough to avoid nerve stimulation, thereby allowing the tissue
to remain somewhat stationary without contractions caused by the electrical energy.

The electrosurgical generator must also have the capability to deliver a relatively wide range of power. The resistance or impedance of the tissue may change radically from point-to-point during the procedure, thereby increasing the power regulation requirements for the electrosurgical generator. For example, a highly fluid-perfused tissue, such as the liver, may exhibit a resistance or impedance in the neighborhood of 40 ohms. Other tissue, such as the marrow of bone, may have an impedance in the neighborhood of 900 ohms. The fat or adipose content of the tissue will increase its impedance. The variable characteristics of the tissue require the electrosurgical generator to be able to deliver effective amounts of power into all types of these tissues, on virtually an instantaneously changing basis as the surgeon moves through and works with the different types of tissues at the surgical site.

These wide variations in power delivery encountered during electrosurgery impose severe performance constraints on the electrosurgical generator. Almost no other electrical amplifier is subject to such rapid response to such widely varying power delivery requirements. Failing to adequately regulate and control the output power may create unnecessary damage to the tissue or injury to the patient or surgical personnel. In a similar manner, failing to adequately establish the electrical characteristics for cutting, coagulating or performing both procedures simultaneously can also result in unnecessary tissue damage or injury.

Almost all electrosurgical generators involve some form of output power monitoring circuitry, used for the purpose of controlling the output power. The extent of power monitoring for regulation purposes varies depending upon the type of mode selected. For example, the coagulation mode of operation does not generally involve sensing the voltage and current delivered and using those measurements to calculate power for the purpose of regulating the output power. However, in the cut mode of operation, it is typical to sense the output current and power and use those values as feedback to regulate the power delivered.
In addition to power regulation capabilities, most electrosurgical generators have the capability of determining error conditions. The output power of the electrosurgical generator is monitored to ensure that electrosurgical energy of the proper power content and characteristics is delivered. An alarm is generated if an error is detected. The alarm may alert the surgeon to a problem and/or shut down or terminate power delivery from the electrosurgical generator.

Certain types of medical equipment controlled by microprocessors or microcontrollers utilize multiple processors for backup and monitoring purposes. Generally speaking, one of the processor serves as a control processor to primarily control the normal functionality of the equipment. Another one of the processors serves as a monitor processor which functions primarily to check the proper operation of the control processor and the other components of the medical equipment. Using one processor for primary control functionality and another processor for primary monitoring functionality has the advantage of achieving redundancy for monitoring purposes, because each processor has the independent capability to shut down or limit the functionality of the medical equipment under error conditions. Standards and recommendations even exist for multiple-processor medical equipment which delineates the responsibilities of the monitoring processors.

**Summary of the Invention**

The present invention has evolved from a desire to achieve a high degree of reliability for monitoring purposes in a multiple-processor electrosurgical generator that delivers electrosurgical energy for surgical procedures. A control processor generates a patterned pulse signal that defines a pattern of pulses that is used to generate output electrosurgical energy. A monitor processor receives the patterned pulse signal and a mode signal indicative of activation of a selected mode of operation of the electrosurgical generator. To determine whether the electrosurgical generator is functioning in the proper selected mode, the monitor processor counts the number of pulses in the patterned pulse signal and compares it to an expected number of pulses for the selected mode. If the counted number of pulses is the same as, or within an acceptable range of, the expected number of pulses, then
the monitor processor determines that the electrosurgical generator is functioning in the selected mode. If the counted number of pulses is not the same as, or not within the acceptable range of, the expected number of pulses, then the monitor processor may take appropriate action, such as issuing an error indication to the surgeon and/or causing the electrosurgical generator to terminate delivery of the electrosurgical energy or to shut down.

In accordance with these improvements, the present invention involves a method of evaluating functionality of an electrosurgical generator. A patterned pulse signal is generated having a plurality of drive pulses. The patterned pulse signal is a signal with which the electrosurgical output power is generated. A number of the drive pulses in the patterned pulse signal is counted. The counted number of drive pulses is compared to an expected number of drive pulses. An error condition is indicated when the counted number of drive pulses and the expected number of drive pulses differ by a predetermined amount, which may preferably be one or more. Additionally, the electrosurgical output power is preferably controlled by adjusting a width of the drive pulses, for which a minimum width may be established. Furthermore, when the width of the drive pulses is about at the minimum width, the patterned pulse signal may preferably still be generated. Also, the method may preferably be combined with performing a power-related check on the electrosurgical output power, and indicating an error condition when a calculated power level is outside of a predetermined range.

Alternatively, the present invention involves a method of evaluating functionality of an electrosurgical generator which delivers electrosurgical output power under a plurality of modes of operation. One of the modes of operation under which the electrosurgical generator is to deliver the electrosurgical output power is indicated. The electrosurgical output power is generated by generating a patterned pulse signal in accordance with the indicated mode of operation. The patterned pulse signal is detected. It is determined from the patterned pulse signal whether the electrosurgical output power is being generated according to the indicated mode of operation. An error condition is then indicated when it is determined that the electrosurgical
output power is not being generated according to the indicated mode of operation.

Additionally, the present invention involves an electrosurgical generator which delivers electrosurgical output power according to a selected mode signal. The electrosurgical generator includes a control processor and a monitor processor. The control processor generates a patterned pulse signal in accordance with the selected mode signal. The patterned pulse signal includes a series of drive pulses which contribute to generating the electrosurgical output power. The monitor processor is connected to the control processor and receives the patterned pulse signal, counts a number of the drive pulses in the patterned pulse signal, determines an expected number of drive pulses in accordance with the selected mode signal, compares the counted number of drive pulses with the expected number of drive pulses and indicates an error condition when the counted number of drive pulses and the expected number of drive pulses differ by a predetermined amount. The electrosurgical generator responds to the indication of the error condition by either issuing an error indication or terminating the delivery of output power.

A more complete appreciation of the present invention and its scope, and the manner in which it achieves the above noted and other improvements, can be obtained by reference to the following detailed description of presently preferred embodiments taken in connection with the accompanying drawings, which are briefly summarized below, and the appended claims.

**Brief Description of the Drawings**

Fig. 1 is a block diagram of a multiple processor electrosurgical generator incorporating the present invention.

Figs. 2, 3 and 4 are waveforms generated in the electrosurgical generator shown in Fig. 1.

Fig. 5 is a flow chart for a procedure for verifying a mode of operation of the electrosurgical generator shown in Fig. 1.

**Detailed Description**

An electrosurgical generator 20, shown in Fig. 1, supplies electrosurgical output voltage and output current at 22, which is conducted to an active electrode (not shown) for monopolar and bipolar electrosurgery. Current is
returned at 24 to the electrosurgical generator 20 from a return electrode (not shown), after having been conducted through the tissue of the patient. The generator 20 is activated to deliver the electrosurgical output power at 22 by activation signals supplied at 26. The activation signal at 26 is asserted upon closing a switch on a handpiece (not shown) which supports the active electrode and is held by the surgeon. The activation signal at 26 may also be asserted from a conventional foot pedal switch (not shown) which is depressed by foot pressure from the surgeon.

The electrosurgical generator 20 includes a system processor 30, a control processor 32, and a monitor processor 34. The system processor 30 generally controls the overall functionality of the electrosurgical generator 20. The system processor 30 includes nonvolatile memory (not shown) containing programmed instructions to be downloaded to the other processors 32 and 34 to establish the functionality of the control and monitor processors 32 and 34. The processors 30, 32 and 34 communicate with each other over a system bus 36. In general, the system processor 30 supervises and controls, at a high level, the entire electrosurgical generator 20. Thus, the system processor 30 supplies a power supply enable signal 37 to the high voltage power supply 38 to enable the high voltage power supply 38. The system processor 30 also supplies an output select signal at 39 to the RF output section 42. The output select signal at 39 causes the RF output section 42 to output the desired electrosurgical energy at 22 to a selected handpiece (not shown) connected to an output connector (not shown) for monopolar or bipolar electrosurgery.

The primary functionality of the control processor 32 is to establish and regulate the power delivered from the electrosurgical generator 20 at 22. The control processor is connected to a high voltage power supply 38, an RF amplifier 40, and an RF output section 42. The high voltage power supply 38 generates a DC operating voltage by rectifying conventional alternating current (AC) power supplied by conventional mains power lines 44, and delivers the DC operating voltage to the RF amplifier 40 at 46. The control processor 32 sets the voltage level for the DC operating voltage at 46 by a voltage-set signal at 48 supplied to the high voltage power supply 38. The RF amplifier 40 converts the DC operating voltage into monopolar drive signals 50 and bipolar drive signals.
52 having an energy content and duty cycle appropriate for the amount of power and the mode of electrosurgical operation which have been selected by the surgeon. The RF output section 42 converts the monopolar and bipolar drive signals 50 and 52 into the RF voltage and current waveforms and supplies those waveforms to the active electrode at 22 as the output power from the electrosurgical generator 20.

The basic function of the monitor processor 34 is to monitor the functionality of the high voltage power supply 38 and the RF output section 42, as well as to monitor the functions of the control processor 32. If the monitor processor 34 detects a discrepancy in the output electrosurgical energy, or a discrepancy in the expected functionality of the control processor 32, a failure mode is indicated and the monitor processor 34 terminates the delivery of output electrosurgical energy from the electrosurgical generator 20.

The processors 30, 32 and 34 are conventional microprocessors, microcontrollers or digital signal processors, all of which are essentially general purpose computers that have been programmed to perform the specific functions of the electrosurgical generator 20.

The electrosurgical generator 20 also includes user input devices 54 which allow the user to select the mode of electrosurgical operation (cut, coagulation or a blend of both) and the desired amount of output power. In general, the input devices 54 are dials and switches that the user manipulates to supply control, mode and other information to the electrosurgical generator. The electrosurgical generator 20 also includes information output displays 56 and indicators 58. The displays 56 and indicators 58 provide feedback, menu options and performance information to the user. The input devices 54 and the output displays 56 and indicators 58 allow the user to set up and manage the operation of the electrosurgical generator 20.

The activation signals at 26 are applied from the finger and foot switches (not shown) to an activation port 62. The system processor 30 reads the activation signals at 26 from the port 62 to control the power delivery from the electrosurgical generator 20. The components 54, 56, 58 and 62 are connected to and communicate with the system processor 30 by a conventional input/output (I/O) peripheral bus 64, which is separate from the system bus 36.
To generate the electrosurgical energy at 22, the control processor 32 sets the voltage level of the DC operating voltage output at 46 from the high voltage power supply 38 by the voltage set signal at 48. The control processor 32 then generates a patterned pulse signal at 66 and sends it to an enable AND logic gate 68, where the patterned pulse signal at 66 is logically ANDed with enable signals 70 and 72 supplied by the system processor 30 and the monitor processor 34, respectively. The output of the enable logic gate 68 is supplied to a line driver 76 and a receiver 78 in series. The output of the line driver 76 and the receiver 78 forms a power driving signal at 80. The power driving signal at 80 is supplied to the RF amplifier 40. The RF amplifier 40 converts the DC operating voltage at 46 into the monopolar and bipolar drive signals at 50 and 52 according to the power driving signal at 80 formed from the patterned pulse signal at 66 output by the control processor 32. The output select signal at 39 from the system processor 30 then causes the RF output section 42 to output either the monopolar or bipolar drive signal at 50 or 52 as the electrosurgical energy at 22 to the selected handpiece (not shown).

The line driver 76 is preferably a conventional op amp. The line driver 76 and receiver 78 preferably isolate the high-voltage electronics of the RF amplifier 40 from the system, control and monitor processors 30, 32 and 34.

To shut down the electrosurgical generator 20 or to terminate the delivery of power from the electrosurgical generator 20, the monitor processor 34 deasserts the monitor enable signal 72 and/or the system processor 30 deasserts the amplifier enable signal 70. The assertion of both enable signals 70 and 72 to the enable logic gate 68 are required for the formation of the power driving signal at 80 from the patterned pulse signal at 66 through the enable logic gate 68, the line driver 76 and the receiver 78. Deasserting either one of the enable signals 70 or 72 prevents the enable logic gate 68 from conducting the patterned pulse signal at 66 through to the line driver 76 and the receiver 78 to form the power driving signal at 80 supplied to the RF amplifier 40. Without the assertion of the power driving signal at 80, the RF amplifier 40 will not deliver the monopolar or bipolar drive signals at 50 and 52 to the RF output section 42, and the electrosurgical generator 20 will not deliver output power or will terminate the delivery of output power.
The patterned pulse signal at 66 is generally a waveform (e.g. 92, 94 and 96, shown in Figs. 2, 3 and 4) formed of a patterned series of drive pulses 98 within a drive cycle 100 that repeats continuously during the selected mode of operation. The waveforms 92, 94 and 96 are examples for cut, coagulation and blend modes of operation, respectively. The pattern of the drive pulses 98, including the time width of each drive cycle 100, is fixed by the system processor 30 in accordance with the selected mode of operation. In most cases, the time width of each drive cycle 100 is approximately the same for the cut, coagulation and blend modes of operation, but the pattern of the drive pulses 98 within the drive cycles 100 are different, as shown in Figs. 2-4.

A continuous uninterrupted sequence of the drive pulses 98 defines the cut pattern (waveform 92), as shown in Fig. 2. A repeating duty cycle application of the drive pulses 98 defines the coagulation pattern (waveform 94) and the blend pattern (waveform 96), as shown in Figs. 3 and 4, respectively. In other words, no drive pulses 98 are delivered for an “off” time 102 during part of the drive cycle 100. Other specialized modes of operation exist as subsets of these three basic modes, and the amounts of coagulation in the coagulation mode and of cutting and coagulation in the blend mode is varied by adjusting the duty cycle of the drive cycle 100. Once the mode is selected, the pattern of drive pulses 98 defined by that selected mode remains unchanged until a different mode is selected. The width of the drive pulses 98, however, may be changed longer or shorter throughout the surgical procedure in order to regulate the output power.

The energy level in the output power at 22 (Fig. 1) is established by the width of the drive pulses 98 and the voltage of the high voltage power supply 38 (Fig. 1). The width of each drive pulse 98 is established by a number of equal-width steps dependent on the period of the clock (not shown) of the control processor 32 (Fig. 1). The number of equal-width steps is established by a pulse width count, which is initially set by the system processor 30 as representing the desired initial pulse width of the drive pulses 98. The amount of power transferred by the RF amplifier 40 (Fig. 1) in response to each drive pulse 98 is directly related to the width of each drive pulse 98. Thus, the width
of the drive pulses 98 is increased and decreased in order to regulate the power output during each electrosurgical procedure.

In order to monitor, or check, the mode of operation, as well as to achieve a high degree of reliability for monitoring purposes, the monitor processor 34 (Fig. 1) receives mode information, or a mode signal, from the system processor 30 (Fig. 1) through the system bus 36 (Fig. 1), and the patterned pulse signal at 66 (Fig. 1) from the control processor 32 (Fig. 1). The mode signal received by the monitor processor 34 includes information regarding the pattern of the drive pulses 98 (Figs. 2-4) for the patterned pulse signal 66 generated by the control processor 32. Thus, the monitor processor 34 has information regarding the expected number of pulses that should be in the patterned pulse signal at 66 in a given amount of time. The monitor processor 34 counts the drive pulses 98 (e.g. typically on the rising edge of each drive pulse 98) in the patterned pulse signal at 66 in the given amount of time and compares the number of drive pulses 98 counted with the number of drive pulses 98 expected. If the difference between the counted and expected number of drive pulses 98 is within an acceptable limit, then it is confirmed that the electrosurgical generator 20 is functioning in the proper mode of operation. Otherwise, if the difference is greater than the acceptable limit, then an error or failure condition is indicated and the monitor processor 34 takes appropriate action, such as causing the electrosurgical generator 20 to issue an error indication, to stop producing the electrosurgical energy and/or to shut down.

The time period during which the monitor processor 34 (Fig. 1) counts the drive pulses 98 (Figs. 2-4) is preferably longer than one drive cycle 100. Additionally, the counting time period is preferably long enough to minimize potential counting errors that may result due to the lack of clock synchronization between the control processor 32 (Fig. 1), which generates the drive pulses 98, and the monitor processor 34 (Fig. 1), which counts the drive pulses 98. An acceptable counting time period is about two to three of the drive cycles 100 or more.

The comparison of the counted and expected number of drive pulses 98 (Figs. 2-4) allows the difference between the counted and expected number of drive pulses 98 to be within an acceptable limit, or range, since the monitor
processor 34 (Fig. 1) may not be synchronized with the operation of the control processor 32 (Fig. 1), particularly since the control and monitor processors 32 and 34 may not operate at the same clock speed. Thus, some error between the counted and expected number of drive pulses 98 may be expected and taken into consideration.

A procedure 104 performed by the monitor processor 34 (Fig. 1) for checking the mode of operation is shown in Fig. 5. The mode checking procedure 104 starts at 106 and waits for activation of the electrosurgical energy at 108. Such activation is generally indicated to the monitor processor 34 by the system processor 30 (Fig. 1) in response to the activation signal at 26 being supplied to the system processor 30. The selected mode of operation is then determined at 110 according to the mode information provided from the system processor 30 to the monitor processor 34. Alternatively, the pattern or number of the drive pulses 98 (Figs. 2, 3 and 4) is supplied to the monitor processor 34 in the mode information. The drive pulses 98, or pulse edges, are then counted in the counting time period at 112. Then it is determined at 114 whether the time length of the indicated activation is greater than the counting time period. If not, then it is assumed that the activation ended before the counting completed at 112, so the count is invalid and cannot be used to verify the mode of operation. Therefore, the count is cleared at 116, and the mode check procedure 104 returns to 108 to wait for the next activation. On the other hand, if the time length of the indicated activation is greater than the counting time period, as determined at 114, then the count is valid. In this case, the difference between the number of counted drive pulses 98 and the number of expected pulses is calculated at 118. The number of expected pulses depends on the selected mode determined at 110 or the pattern, or number, of pulses indicated in the mode information. It is then determined at 120 whether the absolute value of the difference calculated at 118 is greater than an acceptable limit. The acceptable limit is preferably determined empirically and depends on the selected mode. If the absolute value of the difference calculated is greater than the acceptable limit, as determined at 120, then an error is declared at 122 and the mode check procedure 104 ends at 124. On the other hand, if the absolute value of the difference calculated is not greater than the acceptable
limit, as determined at 120, then the count is cleared at 116 and the mode check procedure 104 returns to 108 to wait for the next activation.

The control processor 32 (Fig. 1) is preferably programmed such that, to reduce the power output to almost zero, the width of the drive pulses 98 (Figs. 2-4) of the patterned pulse signal at 66 (Fig. 1) is not decreased to zero, but to a minimum width. At the minimum width, attenuation properties of the line driver 76 and receiver 78 (Fig. 1) render them unable to pass the drive pulses 98 of the patterned pulse signal applied at 66, when received through the enable AND logic gate 68 (Fig. 1). Thus, the minimum width of the drive pulses 98 results in the delivery of no power driving signal at 80 (Fig. 1), which results in no output power from the RF amplifier 40. In this case, since the drive pulses 98 of the patterned pulse signal 66 have not been reduced to zero, but remain at minimally narrow widths, the mode check can still be performed. In other words, the minimum width of the drive pulses 98 enables the mode check performed by the monitor processor 34 (Fig. 1) to be able to determine that the electrosurgical generator 20 is operating in the proper mode, even when no power is being output.

Additionally, rather than basing the mode check on an acceptable limit for the difference between the counted and expected number of drive pulses 98 (Figs. 2-4), as determined at 120 (Fig. 5) of the mode check procedure 104 (Fig. 5), the mode check could require the counted and expected number of drive pulses 98 to be identical. Alternatively, the acceptable limit for the difference may be based on a percentage of the expected number of drive pulses, wherein the percentage is empirically determined for each mode of operation.

The present invention is particularly advantageous in a situation where the monitor processor 34 (Fig. 1) also monitors the power output of the electrosurgical generator 20 (Fig. 1) using a power-related check, as described in U.S. patent application Serial No. 10/299,998, filed 19 November 2002 for Electrosurgical Generator and Method for Cross-Checking Output Power, for example. The aforementioned U.S. patent application describes a power-related check, or monitoring function, incorporated in the electrosurgical generator 20. The monitor processor 34 receives current and voltage feedback
signals 126 and 128 (Fig. 1) from the RF output section 42 (Fig. 1) indicating the current and voltage of the output electrosurgical energy, from which the power level can be calculated. The control processor 32 (Fig. 1) also receives current and voltage feedback signals 130 and 132 (Fig. 1) from the RF output section 42 separately indicating the current and voltage of the output electrosurgical energy, from which the power level can be separately calculated. The power-related check may, thus, ensure that the electrosurgical generator is functioning with the proper power output level given the desired mode of operation and/or that the control processor 32 and the monitor processor 34 have both calculated about the same power output level, as described in the aforementioned U.S. patent application. However, there are situations in which the power-related checks may not produce a correct failure or non-failure indication. For example, the power-related checks have no data on which to base the checks if the power output is at or near zero, which can occur often in normal non-failure electrosurgical situations, as well as in failure conditions. As described above, however, the minimum pulse width enables the mode check to confirm whether the electrosurgical generator is at least functioning in the proper mode, so that a failure condition can be avoided when one is not actually indicated.

Additionally, given the large number and range of modes of operation in electrosurgery, and since there may be a considerable range of allowable power levels for each mode of operation, a proper power output for one mode may resemble a proper power output for a different mode. Thus, the power-related check may determine that the output power is proper for the intended mode of operation and that no error has occurred, even when an error has, in fact, occurred that has caused the electrosurgical generator 20 to operate in the wrong mode. The mode check, though, would detect such a failure.

Thus, the mode check performed by the present invention can detect an error condition that power-related checks cannot detect and can avoid an error condition when power-related checks cannot be performed. The mode check may serve as a backup check for power-related checks.

On the other hand, the power-related check described in the aforementioned U.S. patent application can detect errors that cannot be
detected by the present invention. For instance, even if the mode check
determines that electrosurgical generator 20 (Fig. 1) is delivering the
electrosurgical energy in the selected mode of operation, it is still necessary to
further determine whether the power level of the electrosurgical energy is within
an acceptable range. Thus, the monitor processor 34 (Fig. 1) calculates the
power output from the current and voltage feedback signals 126 and 128 (Fig.
1) from the RF output section 42 (Fig. 1) and determines whether the power
output level is within the acceptable range, dependent on the mode of
operation, as described in the aforementioned U.S. patent application and in
U.S. patent application Serial No. 10/299,953, filed 19 November 2002, for
Electrosurgical Generator and Method with Multiple Semi-Autonomously-
Executable Functions.

The present invention offers the improvement and advantage of being
able to determine whether a failure condition has occurred in many situations
where other checks cannot. The electrosurgical generator can be prevented
from operating under conditions which might possibly cause a risk to the patient
and can be assured of operating under conditions where the output power and
performance of the electrosurgical generator is more reliably delivered. Many
other benefits, advantages and improvements in monitoring the proper
functionality of the electrosurgical generator will also be apparent upon gaining
a full appreciation of the present invention.

Presently preferred embodiments of the invention have been described
with a degree of particularity. This description has been made by way of
preferred example. It should be understood that the scope of the invention is
defined by the following claims, and should not be unnecessarily limited by the
detailed description of the preferred embodiments set forth above.
Claims

1. A method of evaluating functionality of an electrosurgical generator which delivers electrosurgical output power, comprising:
   generating a patterned pulse signal with which the electrosurgical output power is generated, the patterned pulse signal having a plurality of drive pulses;
   counting a number of the drive pulses in the patterned pulse signal;
   comparing the counted number of drive pulses to an expected number of drive pulses; and
   indicating an error condition when the counted number of drive pulses and the expected number of drive pulses differ by a predetermined amount.

2. A method as defined in claim 1 further comprising:
   controlling the electrosurgical output power by adjusting a width of the drive pulses.

3. A method as defined in claim 2 further comprising:
   establishing a minimum width for the drive pulses.

4. A method as defined in claim 1, wherein the electrosurgical output power is dependent on a width of the drive pulses, and further comprising:
   preventing the width of the drive pulses from reducing below a minimum width.

5. A method as defined in claim 4, wherein the electrosurgical generator performs a power-related check on the electrosurgical output power, and further comprising:
   generating the patterned pulse signal having the drive pulses when the width of the drive pulses is about at the minimum width.

6. A method as defined in claim 1 further comprising:
   indicating an error condition when the counted number of drive pulses and the expected number of drive pulses differ by at least one.

7. A method as defined in claim 1 further comprising:
indicating an error condition when the counted number of drive pulses and the expected number of drive pulses differ by a predetermined percentage of the expected number of drive pulses.

8. A method as defined in claim 1 further comprising:
performing a power-related check on the electrosurgical output power, including calculating a power level of the electrosurgical output power; and
indicating an error condition when the calculated power level is outside of a predetermined range.

9. A method as defined in claim 1, wherein the electrosurgical generator includes a control processor which controls the delivery of the electrosurgical output power and also includes a monitor processor which monitors performance of the electrosurgical generator, and further comprising:
generating the patterned pulse signal using the control processor; and
counting the number of drive pulses using the monitor processor.

10. A method as defined in claim 1, wherein the drive pulses in the patterned pulse signal are arranged in a pattern that repeats over successive time periods, and further comprising:
counting the number of the drive pulses in the patterned pulse signal over a counting time period that is greater than at least one of the successive time periods.

11. A method as defined in claim 10 further comprising:
counting the number of the drive pulses in the patterned pulse signal over at least two of the successive time periods.

12. A method as defined in claim 1, wherein the drive pulses in the patterned pulse signal are arranged in a pattern that repeats over successive time periods and that includes a off time during which no pulses occur, and further comprising:
counting the number of the drive pulses in the patterned pulse signal over a counting time period that is sufficiently long to ensure that all of the drive pulses in at least one of the successive time periods are within the counting time period.
13. A method of evaluating functionality of an electrosurgical generator which delivers electrosurgical output power under a plurality of modes of operation, comprising:

indicating one of the modes of operation under which the electrosurgical generator is to deliver the electrosurgical output power;

generating the electrosurgical output power by generating a patterned pulse signal in accordance with the indicated mode of operation;

detecting the driving signal;

determining from the driving signal whether the electrosurgical output power is being generated according to the indicated mode of operation; and

indicating an error condition when it is determined that the electrosurgical output power is not being generated according to the indicated mode of operation.

14. A method as defined in claim 13 further comprising:

reducing the electrosurgical output power to about zero.

15. A method as defined in claim 13 further comprising:

performing a power-related check on the electrosurgical output power, including calculating a power level of the electrosurgical output power; and

indicating an error condition when the calculated power level is outside of a predetermined range dependent on the indicated mode of operation.

16. An electrosurgical generator which delivers electrosurgical output power according to a selected mode signal, comprising:

a control processor which generates a patterned pulse signal in accordance with the selected mode signal, the patterned pulse signal including a series of drive pulses which contribute to generating the electrosurgical output power;

a monitor processor connected to the control processor and which receives the patterned pulse signal, counts a number of the drive pulses in the patterned pulse signal, determines an expected number of drive pulses in accordance with the selected mode signal, compares the counted number of
drive pulses with the expected number of drive pulses and indicates an error condition when the counted number of drive pulses and the expected number of drive pulses differ by a predetermined amount; and

the electrosurgical generator responding to the indication of the error condition by one of either issuing an error indication or terminating the delivery of output power.

17. An electrosurgical generator as defined in claim 16 further comprising:

a system processor connected to the control processor and the monitor processor and which oversees functionality of the control and monitor processors, the system processor generating the selected mode signal and sending the selected mode signal to the control processor and the monitor processor.
START 106

ACTIVATION? 108

YES -> DETERMINE SELECTED MODE 110

COUNT THE NUMBER OF PULSE EDGES IN TIME PERIOD 112

ACTIVATION TIME > COUNT TIME PERIOD? 114

NO -> CLEAR COUNT 116

YES -> DETERMINE THE DIFFERENCE BETWEEN THE PULSE EDGES COUNTED AND THE PULSE EDGES EXPECTED 118

IS THE ABSOLUTE VALUE OF THE DIFFERENCE > A LIMIT? 120

NO -> END 124

YES -> DECLARE ERROR-STOP/TERMINATE COMMAND 122

FIG.5
**INTERNATIONAL SEARCH REPORT**

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC 7 A61B18/12

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

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

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

EPO-Internal, WPI Data, PAJ

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
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Further documents are listed in the continuation of box C. Patent family members are listed in annex.

* Special categories of cited documents:
  * "A" document defining the general state of the art which is not considered to be of particular relevance
  * "E" earlier document but published on or after the international filing date
  * "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
  * "O" document referring to an oral disclosure, use, exhibition or other means
  * "P" document published prior to the international filing date but later than the priority date claimed

**Date of the actual completion of the international search**

10 February 2004

**Date of mailing of the international search report**

19/02/2004

**Name and mailing address of the ISA**

European Patent Office, P.B. 8818 Patentlaan 2 NL – 2280 HV Rijswijk
Tel. (31-70) 340-2040, Tx. 31 881 epo nl, Fax: (31-70) 340-9016

**Authorized officer**

Aronsson, F
**INTERNATIONAL SEARCH REPORT**

**International Application No:** PCT/US 03/34076

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INTERNATIONAL SEARCH REPORT

Box I  Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-15
   because they relate to subject matter not required to be searched by this Authority, namely:
   Rule 39.1(iv) PCT – Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:  
   because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:  
   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II  Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

Form PCT/SA/210 (continuation of first sheet (1)) (July 1998)
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