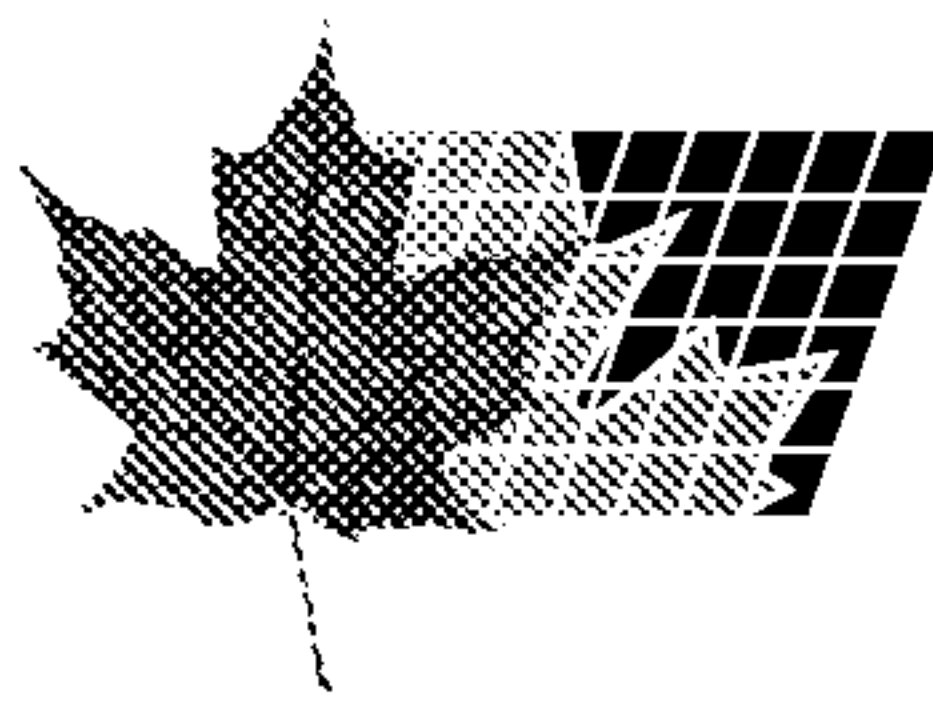
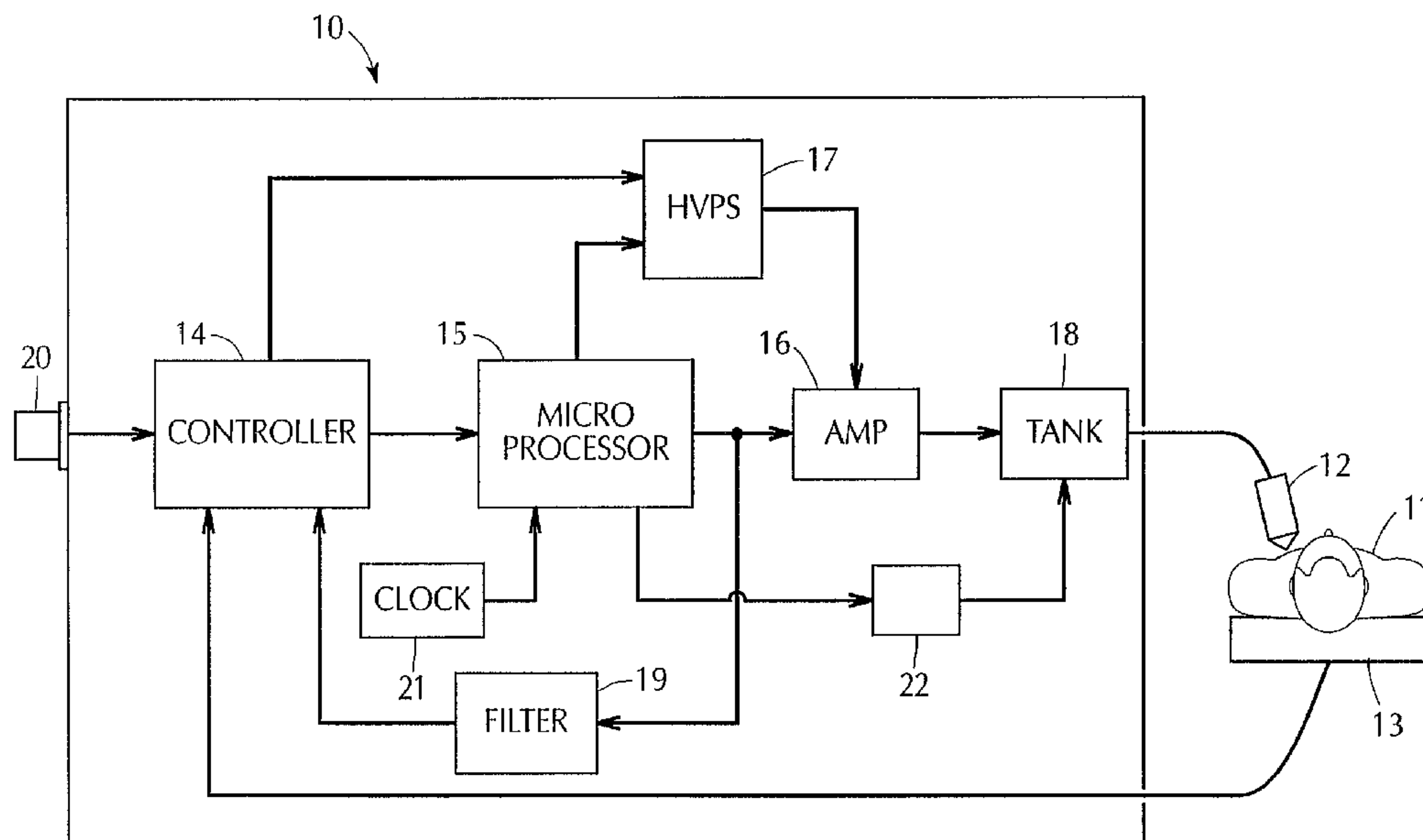




(11) (21) (C) **2,220,909**
(86) 1996/06/03
(87) 1996/12/12
(45) 2001/02/27

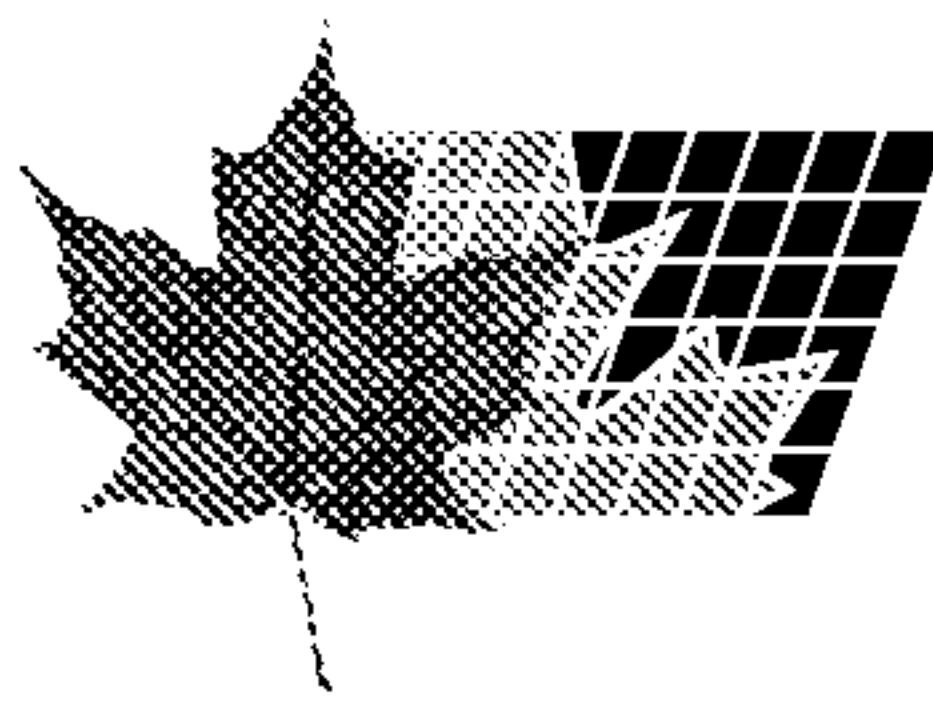
(72) KLICEK, Michael S., US
(72) SODNICAR, Matthew J., US
(73) VALLEYLAB INC., US
(51) Int.Cl.⁶ A61B 17/39
(30) 1995/06/06 (08/471,344) US

(54) **GENERATION NUMERIQUE DE FORMES D'ONDES POUR
GENERATEUR ELECTROCHIRURGICAL**
(54) **DIGITAL WAVEFORM GENERATION FOR
ELECTROSURGICAL GENERATORS**



(57) La présente invention concerne un générateur électrochirurgical (10) utilisant un principe perfectionné de production de formes d'ondes grâce à l'utilisation d'un microprocesseur (15). Les formes d'ondes produites constituent la sortie numérique série d'un microprocesseur (15). Cette sortie numérique série est transformée par un étage amplificateur en sortie électrochirurgicale H.F. Ce principe perfectionné met en oeuvre également un circuit de surveillance assurant la surveillance continue de la sortie numérique série en procédant par un moyennage temporel de la sortie puis par comparaison de cette valeur avec une valeur de seuil.

(57) An electrosurgical generator (10) has an improved design for generating output waveforms using a microprocessor (15). The waveforms are generated in the form of a serial digital output from the microprocessor (15). The serial digital output is transformed into an electrosurgical RF output in an amplifier stage. The improved design also includes a monitoring circuit to continuously monitor the serial digital output by time-averaging the output, and then comparing that value with a threshold. The electrosurgical generator (10) comprises a microprocessor (15), an algorithm in the microprocessor (15) capable of toggling an output port of



(11) (21) (C) **2,220,909**
(86) 1996/06/03
(87) 1996/12/12
(45) 2001/02/27

Un microprocesseur (15) équipant ce générateur électrochirurgical (10) exécute un algorithme permettant la commutation d'un port de sortie du microprocesseur (15), d'un amplificateur de sortie (16), d'une alimentation électrique courant continu H.T. réglable (17), d'un circuit patient à électrode active (12) et électrode retour (13). Le générateur électrochirurgical (10) peut également être équipé d'un sélecteur de mode (20) permettant de faire un choix parmi plusieurs formes d'impulsions dans la sortie numérique série. L'algorithme peut également comporter plusieurs séquences de commande, chaque séquence de commande étant conçue pour produire une forme d'impulsion choisie parmi plusieurs formes d'impulsions. Le générateur peut également comporter un circuit amortisseur à tampon (22) permettant d'atténuer l'amplitude des pointes de tension de la sortie électrochirurgicale et un circuit de suppression d'impulsion. Le circuit de surveillance comporte un filtre passe-bas (19) et un comparateur permettant de vérifier le fonctionnement du générateur de formes d'ondes.

the microprocessor (15), an output amplifier (16), an adjustable high voltage DC power supply (17), a patient circuit including an active electrode (12) and a return electrode (13). The electrosurgical generator (10) may further comprise a mode selector (20) for selecting one of a plurality of pulse patterns in the serial digital output, and a plurality of command sequences in the algorithm, where each command sequence is designed to produce one of the plurality of patterns. There may also be a tank damp circuit (22) for reducing the amplitude of voltage spikes in the electrosurgical output, and a pulse suppression circuit. The monitoring circuit comprises a low pass filter (19) and a comparator to verify operation of the waveform generator.

PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ :**A61B 17/39****A1**

(11) International Publication Number:

WO 96/39088

(43) International Publication Date:

12 December 1996 (12.12.96)

(21) International Application Number: PCT/IB96/00551

(22) International Filing Date: 3 June 1996 (03.06.96)

(30) Priority Data:

08/471,344

6 June 1995 (06.06.95)

US

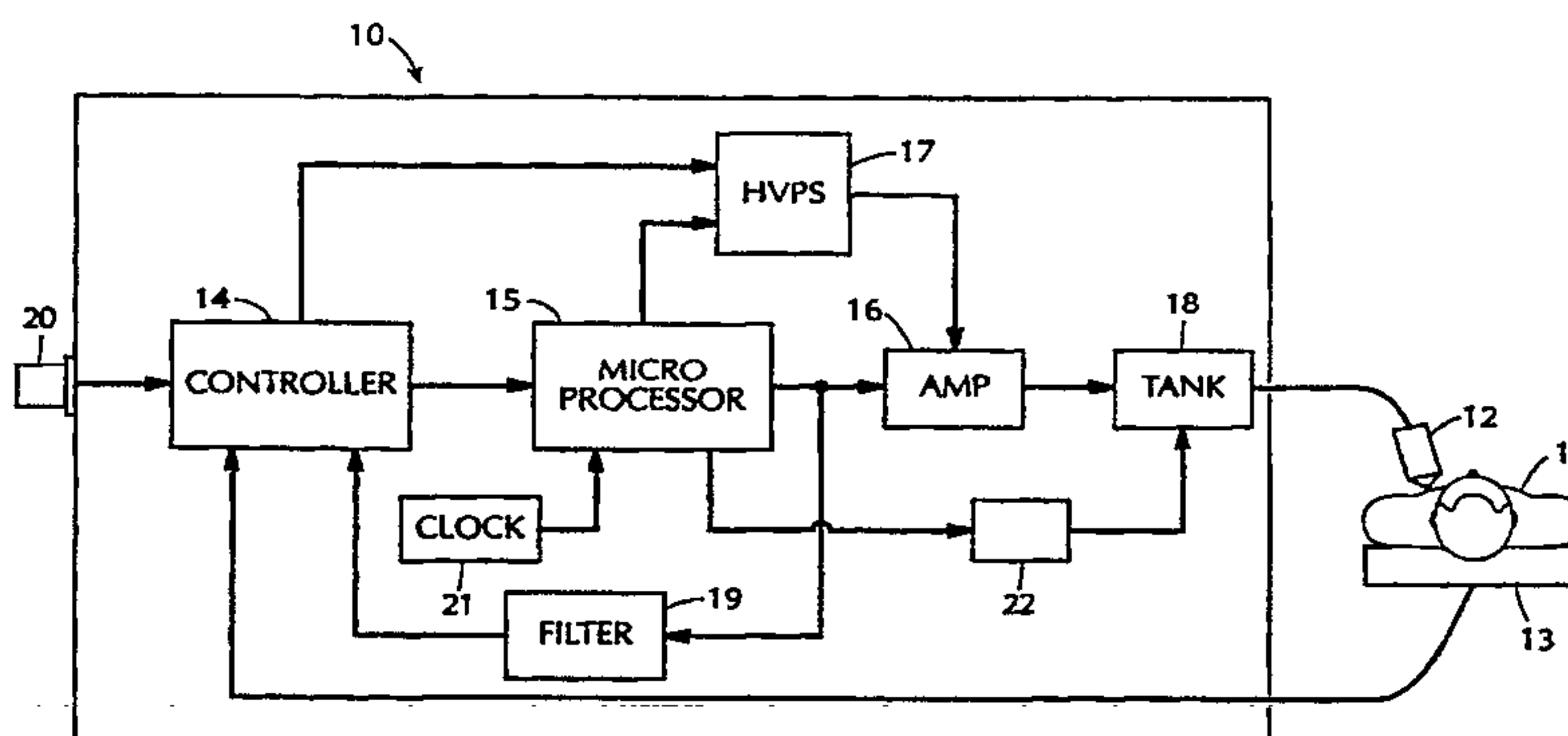
(71) Applicant: VALLEYLAB INC. [US/US]; 5920 Longbow Drive, Boulder, CO 80301 (US).

(72) Inventors: KLICEK, Michael, S.; 2964 Roundtree Drive, Troy, MI 48083 (US). SODNICAR, Matthew, J.; 930 Mercury Drive, Lafayette, CO 80026 (US).

(81) Designated States: AU, CA, DE (Utility model), JP, MX, RU, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published*With international search report.**Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.*

(54) Title: DIGITAL WAVEFORM GENERATION FOR ELECTROSURGICAL GENERATORS



(57) Abstract

An electrosurgical generator (10) has an improved design for generating output waveforms using a microprocessor (15). The waveforms are generated in the form of a serial digital output from the microprocessor (15). The serial digital output is transformed into an electrosurgical RF output in an amplifier stage. The improved design also includes a monitoring circuit to continuously monitor the serial digital output by time-averaging the output, and then comparing that value with a threshold. The electrosurgical generator (10) comprises a microprocessor (15), an algorithm in the microprocessor (15) capable of toggling an output port of the microprocessor (15), an output amplifier (16), an adjustable high voltage DC power supply (17), a patient circuit including an active electrode (12) and a return electrode (13). The electrosurgical generator (10) may further comprise a mode selector (20) for selecting one of a plurality of pulse patterns in the serial digital output, and a plurality of command sequences in the algorithm, where each command sequence is designed to produce one of the plurality of patterns. There may also be a tank damp circuit (22) for reducing the amplitude of voltage spikes in the electrosurgical output, and a pulse suppression circuit. The monitoring circuit comprises a low pass filter (19) and a comparator to verify operation of the waveform generator.

74702-26

1

Related subject matter may be seen in U.S. Patent No. 5,599,344 "Power Control for an Electrosurgical Generator" and U.S. Patent No. 5,628,745 "Exit Spark Control for an Electrosurgical Generator".

5 1. Field of the Invention. This invention pertains to the design of electrosurgical generators, and more particularly to an improved design for generating electrosurgical output waveforms and monitoring those waveforms to verify proper operation.

10 2. Background of the Disclosure. Electrosurgical generators are used for generating high frequency electrical energy for surgical use on the tissue of a patient. The high frequency electrical energy is also referred to as radio-frequency (RF) energy, or as electrosurgical energy. The
15 electrosurgical energy flows through an electrode which is manipulated by a surgeon. The electrode can be used to cut, coagulate, and/or fulgurate the tissue of the patient.

The electrosurgical energy will have an associated waveform. For example, the electrosurgical energy may be in
20 the form of a sine wave. The waveform will also have a duty cycle. For example, the sine waves may not be continuous, and may instead have the cycles separated in time by periods of zero output.

The importance of the waveform for electrosurgical
25 generators is that different waveforms will have different tissue effects. For example, it is well known in the art that a continuous sine wave may have desirable tissue cutting characteristics. Other waveforms, such as high frequency white noise, may have desirable tissue fulguration characteristics.

74702-26

2

One of the important capabilities of electrosurgical generators is that the output waveform can be selected by the surgeon to achieve the desired surgical effect. The surgeon may sometimes desire a combination of cutting and coagulation effects, which is sometimes called a "blend" mode. To achieve these blend modes, designers of electrosurgical generators may experiment with different waveforms and duty cycles to achieve the best possible tissue effects. The commercial success of electrosurgical generators is partly based on the desirability and effectiveness of the modes or waveforms.

Digital technology has been used in prior electrosurgical generators. For example, U.S. Patent number 4,658,819 discloses an electrosurgical generator with a microprocessor controller that is used to decrease the output power with increasing patient impedance. However, there is no disclosure of digital waveform generation.

Some currently available electrosurgical generators use analog circuitry to generate the output waveforms. Other currently available electrosurgical generators use digital technology to generate output waveforms. U.S. Patent number 4,658,820 discloses a waveform generator that stores several waveforms in an MxN storage device. The storage device is loaded in a parallel fashion, and then a shift register is used to sequentially output each bit into a serial data stream.

Similarly, U.S. Patent number 4,961,739 discloses another digital waveform generator in which the storage device has an MxNxP storage capability with an improved memory access capability. This waveform generator allows for a greater diversity of waveforms, waveform lengths, and waveform frequencies. A shift register is also used in this waveform

74702-26

3

generator to convert a parallel data stream into a serial output.

Both of the foregoing digital waveform generators require hardware and circuitry associated with a shift register. It would be desirable to have a microprocessor-based signal generator that could digitally generate commands for different waveforms without the added complexity and other restraints associated with a shift register. It would also be desirable to have a fault detection circuit for the waveform generator to ensure proper operation.

SUMMARY OF THE INVENTION

An improved electrosurgical generator uses a microprocessor for waveform generation. The microprocessor has an algorithm that is capable of toggling an output port of the microprocessor to generate many different waveforms. No shift register is required. A fault detection circuit can check the output of the waveform generator to insure proper operation.

Independent apparatus claims 1, 2 and 3 clearly distinguish over the Altendorf patent (5,167,660). In the present invention, the dosage error monitoring circuit comprises a filter for time averaging the serial digital output and a comparator for comparing the filtered serial digital output against at least one safety threshold. An output amplifier is also electrically connected to the serial digital output which is capable of receiving and transforming the serial digital output into high frequency electrosurgical energy. The adjustable high voltage DC power supply is in electrical communication with the output amplifier for adjusting the amplitude of the high frequency. The pulse generator and output amplifier generate the desired frequency and duty cycle directly.

74702-26

3a

Altendorf is directed to a device which supplies a reference value to a comparator to compare to an operating voltage for forming a control signal to maintain the operating voltage at a constant level. The microprocessor forms a
5 reference value from the modulation signal of the generator and from a prescribed setting signal. Altendorf does not disclose the dosage monitoring circuit and amplifier as described above and recited in the claims of the present application.

An electrosurgical generator may be used for applying
10 high frequency electrosurgical energy to the tissue and bodily fluids of a patient. The microprocessor in the electrosurgical generator may have a memory capability, at least one output port, and at least one input port. A clock signal may be connected to one of the input ports of the microprocessor to
15 provide a reference frequency.

An algorithm in the microprocessor is designed to execute a command sequence for toggling the output port. A serial digital output from the output port may thereby be created. The algorithm may be designed to continuously execute
20 until it is reset through one of the input ports of the microprocessor.

The output amplifier in the electrosurgical generator is capable of transforming the serial digital output into the high frequency electrosurgical energy. A field effects
25 transistor (FET) driver circuit and a FET are most preferably included in the output amplifier. An adjustable high voltage DC power supply in electrical connection with the output amplifier may be used for adjusting the amplitude of the high frequency electrosurgical energy.

30 The patient circuit connected to the electrosurgical generator may include an active electrode in electrical

74702-26

3b

connection with the high frequency electrosurgical energy, and a return electrode in electrical connection with the electrosurgical generator.

A mode selector on the electrosurgical generator may
5 be used for selecting one of a plurality of pulse patterns in the serial digital output. Each pattern results in a different effect on the tissue and bodily fluids of the patient. A plurality of command sequences may be in the algorithm. Each command sequence is designed to produce one of the plurality of
10 pulse patterns.

A tank damp circuit may be connected to the output amplifier and may be controlled by the microprocessor for reducing the amplitude of voltage spikes in the electrosurgical energy. A pulse suppression circuit may also be connected to
15 suppress portions of the serial digital output.

The dosage error monitoring circuit in general can time-average the serial digital

output, and then compare that average to a safety threshold. A low-pass filter may be used to time-average the output, although other filtering and averaging techniques can be used. If a safety threshold is reached, the dosage error monitoring circuit may be used to reduce the electrosurgical output substantially to zero.

5 A method of using an electrosurgical generator comprises the following steps: providing a microprocessor in the electrosurgical generator with a memory capability, at least one output port, and at least one input port; creating a serial digital output from the output port of the microprocessor by executing a command sequence in an algorithm in the microprocessor; transforming the serial digital output into the high
10 frequency electrosurgical energy using an output amplifier in the electrosurgical generator; adjusting the amplitude of the high frequency electrosurgical energy with an adjustable high voltage DC power supply in electrical connection with the output amplifier, and connecting a patient circuit to the electrosurgical generator. The patient circuit may include an active electrode in electrical connection with the high
15 frequency electrosurgical energy, and a return electrode in electrical connection with the electrosurgical generator.

Some additional steps in the method of using an electrosurgical generator can be: selecting one of a plurality of pulse patterns in the serial digital output using a mode selector on the electrosurgical generator, where each pattern results in a
20 different effect on the tissue and bodily fluids of the patient, and providing a plurality of command sequences in the algorithm, wherein each command sequence is designed to produce one of the plurality of patterns.

The method may further comprise the step of continuously executing the command sequence until it is reset through one of the input ports of the
25 microprocessor. The method can also comprise the step of reducing the amplitude of voltage spikes in the electrosurgical energy with a tank damp circuit which is connected to the output amplifier and is controlled by the microprocessor. There may also be a step of suppressing portions of the serial digital output using a pulse suppression circuit which is connected to the serial digital output.

30 The method may also comprise the steps of: time averaging the serial digital output; comparing the time-averaged serial digital output against a safety threshold, and reducing the electrosurgical energy substantially to zero whenever the time-averaged serial digital output exceeds the safety threshold.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a functional block diagram of an electrosurgical generator.

Figure 2 is a schematic block diagram of a microprocessor and associated
5 circuits for generating waveforms.

DETAILED DESCRIPTION OF THE INVENTION

Figure 1 is a partial block diagram of an electrosurgical generator 10 connected to a patient 11 by an active electrode 12 and a return electrode 13. The controller 14 is composed of several microcontrollers, logic circuits, and digital
10 memory. In the preferred embodiment, these microcontrollers are Phillips/Sigmetics model 80C562. The microprocessor 15 generates a serial digital output which is subsequently used as an RF mask to generate the output waveform. An output amplifier 16 converts the serial digital output into an electrosurgical signal using a field effects transistor (FET). The output amplifier 16 also includes a tank circuit 18
15 which has been shown as a separate block in Figure 2.

The output amplifier 16 also has an input from an adjustable high voltage power supply 17 which effects the amplitude of the electrosurgical signal. The controller 14 and the microprocessor 15 each have inputs to the adjustable high voltage power supply 17. In the preferred embodiment, the serial digital line from
20 the microprocessor 15 is sent through a low-pass filter 19 which time-averages the serial digital line. The time-averaged, or filtered, signal is sent to the controller 14. For each waveform, the controller 14 has thresholds for the expected value of the filtered signal. If the filtered signal is outside of the thresholds, an algorithm in the controller 14 will generate a fault signal which shuts off the output of the
25 electrosurgical generator 10.

The modes for the electrosurgical generator 10 are selected from a mode selector 20 which sends a signal to the controller 14. Thresholds for the filtered signal are set in the controller 14, and the mode selection is sent to the microprocessor 15. An algorithm in the microprocessor 15 executes one of a
30 plurality of command sequences based on the mode selection. Each command sequence generates a different serial digital output. A clock 21 sends timed pulses to the microprocessor 15 to sequence the execution of the algorithm in the microprocessor 15.

Figure 2 shows a schematic diagram of the microprocessor 15 and some of its associated circuits. In the preferred embodiment, the microprocessor 15 is a Phillips/Signetics 87C750 which is driven with a clock operating at 28.322 MHz. The microprocessor 15 has on-board memory and input ports for the clock 21, as well as other logic signals. An input from the controller 14 which enables the serial digital output is labeled "T_ON_EN" in Figure 2. The output of the mode selector 20 is input to the microprocessor 15 through one of the ports labeled, in Figure 2, "MODE 0" through "MODE 3."

The microprocessor 15 has output ports to deliver the serial digital line and other logic signals. In Figure 2, the serial digital line is labeled "T_ON_MICRO." An output which controls the high voltage power supply 17 is labeled "ECON_GAIN."

In the preferred embodiment, the algorithm in the microprocessor 15 repetitively executes a series of commands that toggle the output port, "T_ON_MICRO," of the microprocessor 15. In this disclosure, the term "toggle" means switching between a logic "on" and a logic "off" in a timed sequence to produce a serial digital output. The series of commands will be different depending on the mode which the surgeon selects. For example, in a pure cut mode, the algorithm will produce a square wave. In a blend mode, the algorithm may reduce the duty cycle by incorporating longer periods of logic "off" in the serial digital output. For one mode, i.e. the electrosurgical spray mode, a 256 byte long lookup table is stored in on-board memory which has the effect of generating a specified waveform output. The pattern will repeat each time the algorithm cycles through the lookup table.

In the preferred embodiment there is also a tank damp circuit which is shown in Figure 1 as block 22. The purpose of the tank damp circuit is to reduce the amplitude of voltage spikes in the electrosurgical output and also to reduce the leakage current. The tank damp circuit 22 is enabled by the microprocessor 15 through an output port labeled "TNK_DMP." The output is sent through NAND gates U10C and U10D where it is logically Nanded with a high impedance flag labeled "HI_Z." The logical output is labeled "TNK_DMP_OUT" and is sent to the tank damp circuit 22.

In the preferred embodiment there is also a pulse suppression circuit shown in Figure 2 as the logical NAND gate labeled U10; its purpose is to lower the duty

cycle of the output by suppressing selected pulses from the serial digital pulse train. The pulse suppression circuit is enabled by the controller 14 when a lower duty cycle is desirable, depending on the mode selected and on the impedance of the patient tissue 11. A digital signal labeled WAK is NAND'ED with the serial digital pulse train 5 at U10B to yield the signal "T_ON" which is sent to the output amplifier 16, as shown in Figure 2.

The preferred embodiment also has a dosage error monitoring circuit composed of a filter 19 and an algorithm in the controller 14. The preferred filter 19 is shown in Figure 2 as a low-pass filter including resistor R15 and capacitor C16. 10 The filtered signal, labeled "T_ON_AVG", is compared with a threshold in the controller 14 to determine if the proper waveform is being generated. If the filtered signal is too high or too low with respect to the threshold for the desired signal, then a fault condition exists and the electrosurgical generator 10 output is shut off.

It is to be understood that the above detailed description of an embodiment 15 of the invention is provided by way of example only. Various details of design and construction may be modified without departing from the true spirit and scope of the invention as set forth in the claims.

74702-26

8

CLAIMS:

1. An electrosurgical generator 10 for applying high frequency electrosurgical energy to a patient 11 comprising:

5 a pulse generator 15 in the electrosurgical generator 10 having a serial digital output;

a dosage error monitoring circuit electrically connected to the serial digital output, the dosage error monitoring circuit comprising a filter 19 connected for time averaging the serial digital output and a comparator for
10 comparing the filtered serial digital output against at least one safety threshold, the dosage error monitoring circuit also being electrically connected to terminate the high frequency electrosurgical energy to the patient when the filtered serial digital output exceeds the at least one safety threshold;

15 an output amplifier 16 electrically connected to the serial digital output within the electrosurgical generator capable of receiving and transforming the serial digital output into the high frequency electrosurgical energy;

20 an adjustable high voltage DC power supply 17 in electrical connection with the output amplifier for adjusting the amplitude of the high frequency electrosurgical energy, and

a patient circuit connected to the electrosurgical generator, the patient circuit including an active electrode 12 in electrical connection with the high frequency
25 electrosurgical energy, and a return electrode 13 in electrical connection with the electrosurgical generator.

2. An electrosurgical generator 10 for applying amplitude adjusted high frequency electrosurgical energy to a patient, the electrosurgical generator 10 having a pulse

74702-26

9

generator 15 for providing a serial digital output, an output amplifier 16 for converting the serial digital output into high frequency electrosurgical energy, an adjustable high voltage DC power supply for adjusting amplitudes of the high frequency electrosurgical energy, and connections for providing the amplitude adjusted high frequency electrosurgical energy to an active electrode 12 and, thereby, the patient and for receiving the amplitude adjusted high frequency electrosurgical energy from the patient with a return electrode 13, characterized in that:

a dosage error monitoring circuit 19 also receives the serial digital output, the dosage error monitoring circuit having a filter for time averaging the serial digital output and a comparator for comparing the time averaged serial digital output with at least one safety threshold and at least substantially terminating the amplitude adjusted high frequency electrosurgical energy when the time averaged serial digital output exceeds the at least one safety threshold.

3. An electrosurgical generator 10 for applying high frequency electrosurgical energy to a patient 11 comprising:

a pulse generator in the electrosurgical generator 10 for creating a serial digital output;

a dosage error monitoring circuit comprising a filter 19 connected for time averaging the serial digital output and a comparator for comparing the filtered serial digital output against a safety threshold;

an output amplifier 16 in the electrosurgical generator 10 capable of receiving and transforming the serial digital output into the high frequency electrosurgical energy;

74702-26

10

an adjustable high voltage DC power supply 17 in electrical connection with the output amplifier 16 for adjusting the amplitude of the high frequency electrosurgical energy, and

- 5 a patient circuit connected to the electrosurgical generator 10, the patient circuit including an active electrode 12 in electrical connection with the high frequency electrosurgical energy, and a return electrode 13 in electrical connection with the electrosurgical generator 10.

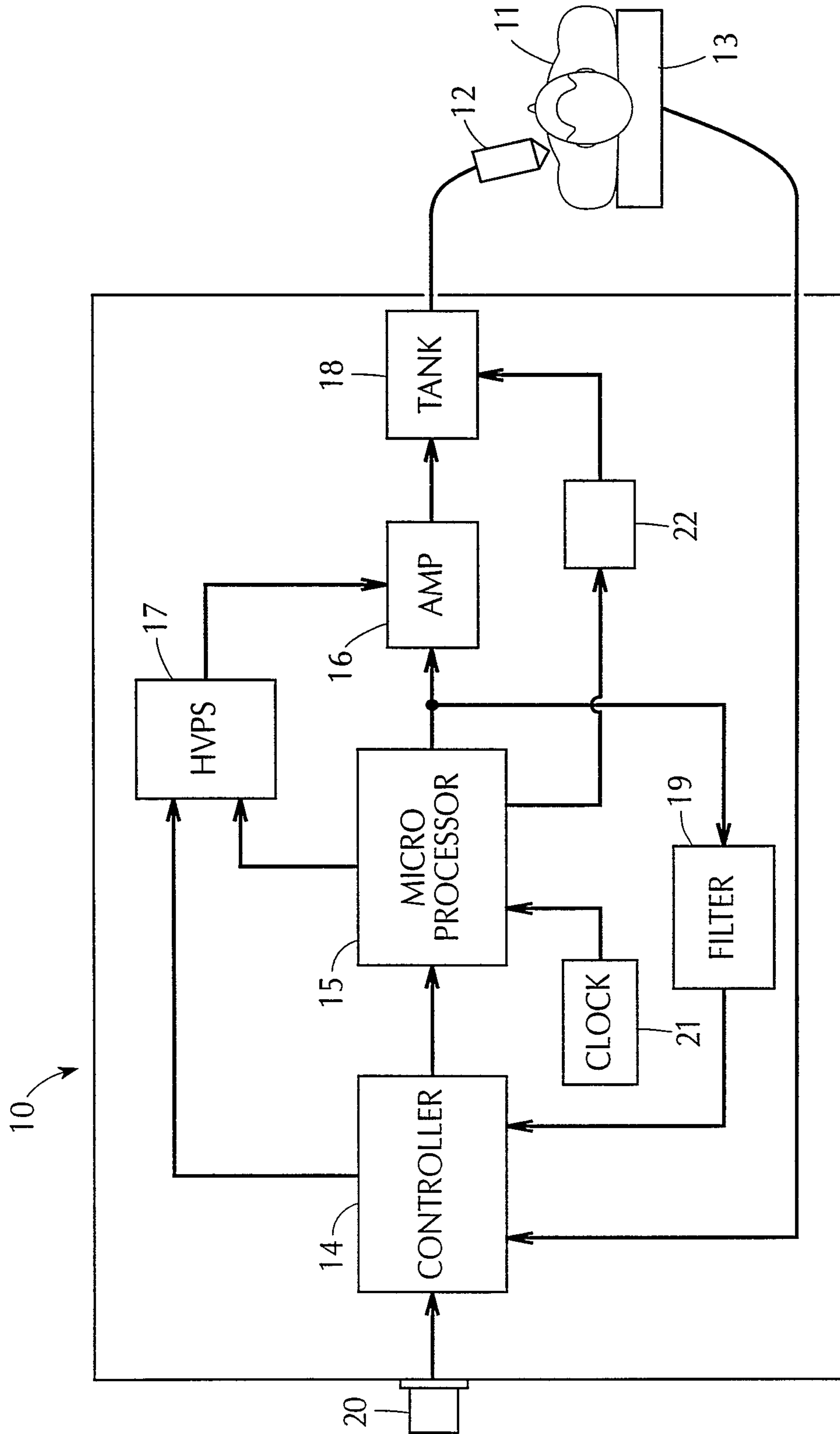
SMART & BIGGAR

OTTAWA, CANADA

PATENT AGENTS

1/2

FIG. 1



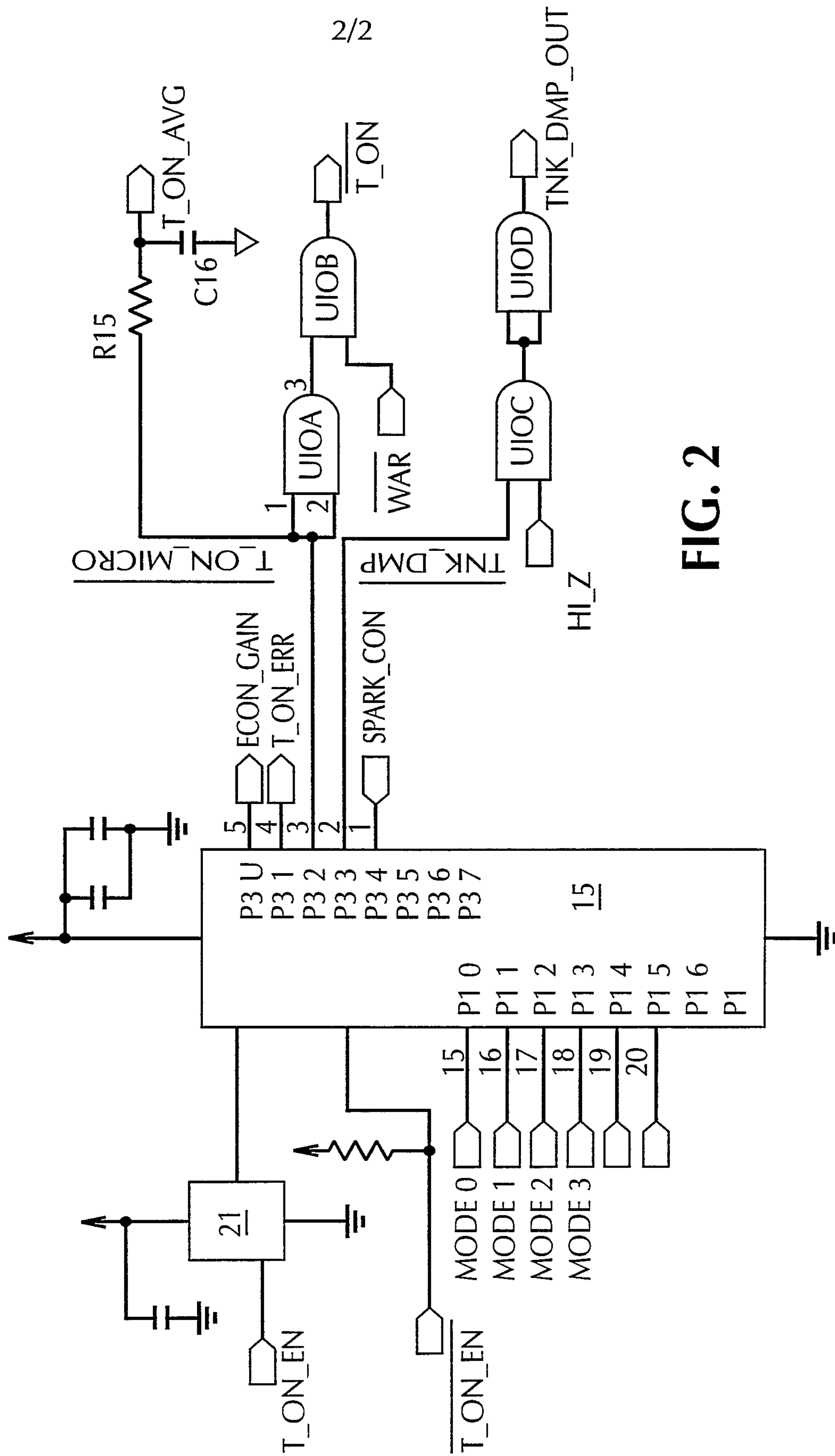


FIG. 2

