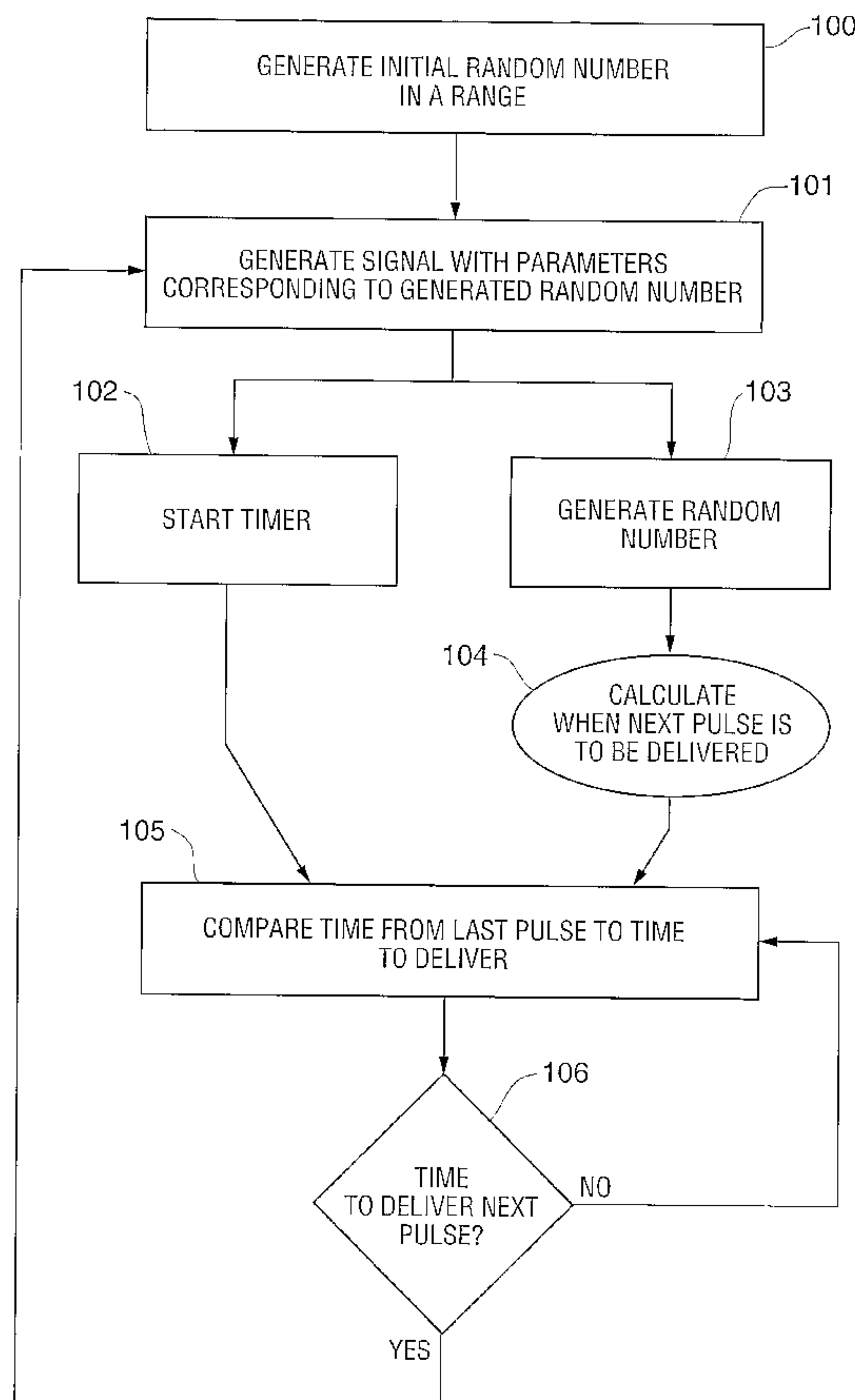




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A device, system and method for stimulating a digestive organ is provided where the stimulation is randomized.

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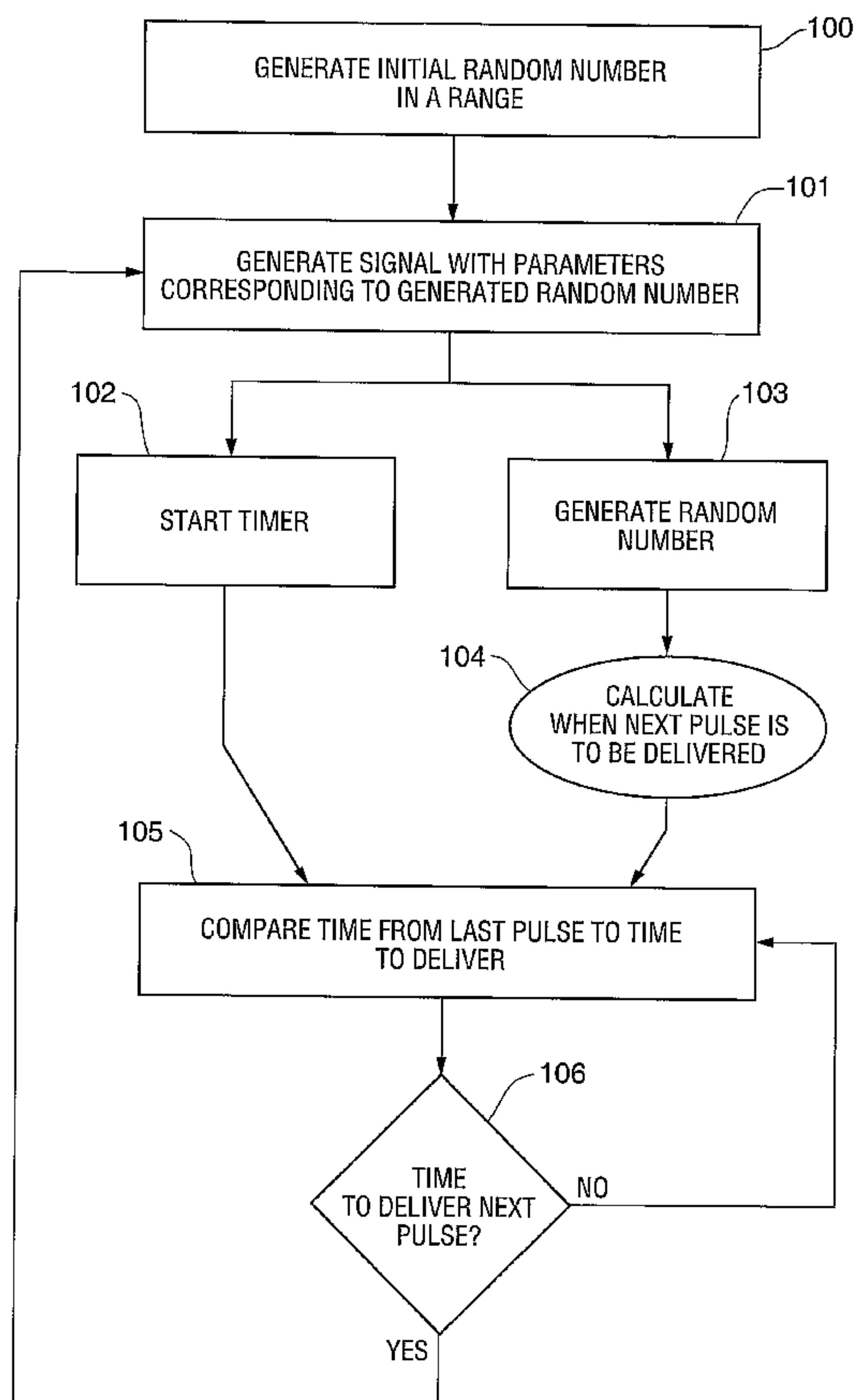
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**RANDOMIZED STIMULATION OF A GASTROINTESTINAL ORGAN**

## CROSS-REFERENCES TO RELATED APPLICATIONS

5 [0001] This application is a nonprovisional application which claims the benefit of priority from U.S. Patent Application No. 11/219,004 filed September 9, 1996, the full disclosure of which is incorporated herein by reference.

STATEMENT AS TO RIGHTS TO INVENTIONS MADE UNDER  
FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

10 [0002] NOT APPLICABLE

REFERENCE TO A "SEQUENCE LISTING," A TABLE, OR A COMPUTER  
PROGRAM LISTING APPENDIX SUBMITTED ON A COMPACT DISK.

15 [0003] NOT APPLICABLE

## BACKGROUND OF THE INVENTION

[0004] Field of Invention

[0005] This invention relates to a device system and method for stimulating the stomach wall.

20 [0006] A number of devices have been proposed to stimulate the stomach wall of a stomach and other gastrointestinal organs. A variety of different stimulation parameters have been proposed.

25 [0007] However, there is belief that with existing proposed devices and stimulation parameters the stomach gastrointestinal or other digestive organs will adapt or become desensitized to stimulation, especially if such stimulation is delivered at non-physiologic rates for a relatively long time. Accordingly it would be desirable to provide a digestive organ stimulation device, system and/or method that may reduce adaptation or desensitization to stimulation.

30 [0008] Some devices have proposed using multiple electrodes in a phased relationship for stimulating digestive tract organs, in some cases, along a peristaltic flow path. However, there

is also some belief that the stomach, gastrointestinal, or other digestive organs will adapt to such phased stimulation over time. Accordingly, it would be desirable to provide a digestive organ stimulation device, system and/or method that may reduce adaptation and/or desensitization to stimulation with multiple electrodes.

5

#### BRIEF SUMMARY OF THE INVENTION

[0009] The present invention provides a device, system and method for randomized stimulation of a digestive organ.

[0010] One aspect of the invention provides a device system and method directed to reducing adaptation or desensitization for a digestive organ to electrical stimulation. According to one aspect of the invention, a device is provided that is programmed to pseudorandomly select stimulation parameters and to deliver pseudorandom stimulation to a digestive organ. Pseudorandom as used herein is intended to include random selection within preset criteria or constraints. Such constraints or criteria may include, for example, stimulation within pre-selected or predetermined stimulation parameter windows. Any of a wide variety of alternative known or proprietary methods and devices for computing, generating, and/or selecting pseudorandom parameters may also be employed. The selected random or pseudorandom stimulation parameters will typically be sufficiently irregular or aperiodic to inhibit tissue adaptation.

[0011] The present invention includes those inventions as claimed in the claims set forth herein.

[0012] Various embodiments and various aspects of the invention are described in the following detailed description.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0013] Figure 1 is a schematic illustration of an exemplary stimulation signal that has been applied to digestive organs.

[0014] Figure 2 is a schematic illustration of an exemplary stimulation signal that has been applied to digestive organs.

[0015] Figure 3 is a schematic illustration of exemplary phased stimulation using a plurality of electrodes.

[0016] Figure 4 is a schematic illustration of a stimulation signal in accordance with the invention.

[0017] Figure 5 is a schematic illustration of a stimulation signal in accordance with the invention.

5 [0018] Figure 6 is a schematic illustration of a stimulation signal in accordance with the invention.

[0019] Figure 7 is a schematic illustration of a stimulation signal in accordance with the invention.

10 [0020] Figure 8 is a schematic illustration of a stimulation signal in accordance with the invention.

[0021] Figure 9 is a schematic illustration of a stimulation signal in accordance with the invention.

[0022] Figure 10 is a flow chart illustrating operation of a stimulation device in accordance with the invention.

15 [0023] Figure 11 is a flow chart illustrating operation of a stimulation device in accordance with the invention.

[0024] Figure 12 is a stimulation device in accordance with the invention.

#### DETAILED DESCRIPTION OF THE INVENTION

20 [0025] According to one aspect of the invention a device for stimulating a digestive organ is provided. The device may stimulate any one or more digestive organs, including for example, portions of the gastrointestinal tract, or digestive organs that secrete digestive substances, digestive regulating hormones, or the like. According to one embodiment, a device for stimulating a stomach is provided.

25 [0026] Stimulation may be provided to elicit one or more desired effects or responses. Stimulation may be provided to control digestion, create sensation of satiety, to control movement of food within the gastrointestinal tract, to regulate digestive processes or to regulate hunger, among other things. One example of such a stimulating device is described in U.S. Patent No. 6,535,764, incorporated herein by reference.

[0027] According to one aspect of the invention, a device is provided that is programmed to randomly (or pseudorandomly) select or vary one or more stimulation parameters, and to deliver the stimulation to a digestive organ according to the selected parameters. In accordance with one aspect, stimulation is randomly (or pseudorandomly) selected or varied to reduce  
5 adaptation or desensitization of a digestive organ to stimulation, and especially to stimulation at non-physiologic rates.

[0028] The programmed device may randomly (or pseudorandomly) select or generate parameters from within a window of acceptable parameters or a randomization window. Such parameters may include but are not limited to, e.g., pulse width, pulse repetition rate, burst  
10 frequency, burst repetition rate, pulses per burst. The programmed device may also randomly (or pseudorandomly) select or vary pulse amplitude, pulse shape and burst envelope within a window or according to selection criteria. The programmed device may randomly (or pseudorandomly) select or vary any one or more of these or other parameters prior to or during stimulation.

[0029] The programmed device may also randomly (or pseudorandomly) select or vary  
15 stimulation from pulse to pulse or burst to burst. The programmed device may operate to periodically change parameters or may do so in response to sensing or receiving feedback that adaptation or desensitization is occurring, or that the stimulation is otherwise losing its effectiveness. According to one aspect of the invention, for example, the device may monitor  
20 stimulation response over time using a contraction monitoring device such as a strain gauge or other contraction sensor. If the device detects a sub optimal stimulation response, the device may then randomly or pseudorandomly select the next parameter(s) or sets of parameters.

[0030] According to another aspect of the invention the programmed device may randomly (or pseudorandomly) select or vary stimulation at multiple stimulation sites. Each of such sites  
25 may have electrically separate stimulating electrodes where the stimulation parameter at each site is independent of the stimulation at the other sites. The stimulation sequence or timing of the sequence may also be randomly (or pseudorandomly) selected or varied. Thus, there is no specific phasing of stimulation at the various sites.

[0031] Referring to Figure 1, an example of a typical stimulation signal that has been used to  
30 stimulate digestive organs is illustrated. The signal comprises a series of pulses. The pulses have a pulse amplitude of PA1, a pulse width of PW1 and repeat at a pulse repetition rate of PRR1. The pulse repetition rate is the time of initiation of a pulse to the time of initiation of

the next pulse. The parameters are generally preset or otherwise selected or chosen for treatment.

[0032] Referring to Figure 2, an example of a typical stimulation signal that has been used to stimulate digestive tract organs is illustrated. The signal comprises a pattern of repeating  
5 bursts of pulses that repeat at a burst repetition rate of BRR2. That is, the burst repetition rate is the time of the initiation of a burst to the initiation of a subsequent burst. The pulses within the burst have a pulse amplitude of PA and burst frequency of BF2. The bursts have a duration of BD2 and include a certain number of pulses per bursts PPB2. These parameters are generally preset or otherwise selected for treatment.

10 [0033] Referring to Figure 3, an example of typical multi-electrode stimulation is illustrated. A stimulation signal is delivered through Electrode 1. Stimulation at Electrode 2 is phased from the stimulation signal at Electrode 1 at phase angle,  $\Psi$ , which represents a time between which the signal at Electrode 1 is initiated and the signal at Electrode 2 is initiated. The signal at Electrode 1 and Electrode 2 may also overlap.

15 [0034] Figure 4 illustrates an example of a randomized stimulation signal that, in accordance with the invention, may be randomly (or pseudorandomly) selected by a programmed device and delivered to a digestive organ. The signal illustrated in Figure 4 randomly varies in pulse width the first pulse width is PWA, the second is PWb, the third is PWc and the fourth is PWD. These pulse widths are selected and delivered. The pulse widths may be in a pre-selected  
20 range of pulse widths. For example in one variation they may vary from 1-20 pulses per minute.

[0035] Figure 5 illustrates an example of a signal that may be randomly (or pseudorandomly) selected by a programmed device and delivered by a device or system in accordance with the invention. The pulses repeat at varying and random rates. The first pulse has a pulse repetition  
25 rate of PRRa after which the second pulse is initiated. The second pulse has a pulse repetition rate of PRRb after which the third pulse is initiated. The third pulse has a pulse repetition rate of PRRc after which the fourth pulse is initiated. The fourth pulse has a pulse repetition rate of PRRd after which the fifth pulse is initiated. The fifth pulse has a pulse repetition rate of PRRe after which the sixth pulse is initiated. The pulse widths or other parameters may or may not  
30 vary as well.

[0036] Figure 6 illustrates an example of a randomized signal that may be randomly (or pseudorandomly) selected and delivered by a programmed device or system or in accordance



with a method of the invention. The stimulation signal comprises a series of bursts of pulses. The bursts of pulses repeat at varying randomized rates. The first burst has a burst repetition rate of BRRa, the second burst has a burst repetition rate of BRRb and the third burst has a burst repetition rate of BRRc. The burst frequency or other parameters may vary as well.

5 [0037] Figure 7 illustrates an example of a randomized signal that may be randomly (or pseudorandomly) selected and delivered by a programmed device or system in accordance with the invention. The stimulation signal comprises a series of bursts of pulses. The frequency of the bursts is randomly varied. The first burst of pulses has a frequency of BFa, the second burst of pulses has a frequency of BFb and the third burst of pulses has a frequency of BFc.  
10 Other parameters may vary as well.

[0038] Figure 8 illustrates an example of a randomized signal that may be randomly (or pseudorandomly) selected and delivered by a device of system or in accordance with the invention. The stimulation signal comprises a series of bursts of pulses. Both the frequency of the pulses and the burst repetition rate randomly vary. The first burst has a frequency of BFD and a burst repetition rate of BRRd. The second burst has a frequency of BFe and a burst repetition rate of BRRe. The third burst has a frequency of BFf and a burst repetition rate of BRRf.  
15

[0039] The randomized signals illustrated in Figure 4-8 are examples of some parameters that may be randomized in a stimulation signal protocol. Any one or more of these parameters may be randomized in any one treatment protocol. The randomized parameters may include but are not limited to one or more of the following: pulse width, pulse amplitude, pulse repetition rate, burst frequency, burst repetition rate. Also, the shape of each pulse including pulses within a burst may vary. The shape of the envelope of pulses of a burst may vary. The frequency, pulse widths and amplitudes within a burst of pulses may also vary. Also, some parameters may vary while others are held constant.  
20  
25

[0040] The various randomized parameters may be randomly (or pseudorandomly) selected from within a window or group of parameters by a random number generator or controller. The window or group of parameters may be preprogrammed into the stimulation device and randomly selected during treatment.

30 [0041] Figure 9 illustrates randomization of signals such as those described with respect to Figures 4-8, applied randomly at a plurality of electrode sites. As shown in Figure 9 a first pulse p1 is applied at electrode 1 at time ta and a second pulse is applied at electrode 2 p2 at

time  $t_b$  within the first time period  $t_1$ . Within time period  $t_2$ , a pulse  $p_3$  is applied at electrode 1 and a pulse  $p_4$  is applied electrode 2 at randomly different times. Similarly pulses at electrodes 1 and 2 are applied at different times during time periods  $t_3$  and  $t_4$ .

[0042] Referring now to Figure 12, a schematic view of a stimulator 120 in accordance with the invention is illustrated. Digestive organ stimulators may include any stimulator that comprises an electrode electrically coupled to a digestive organ and configured to deliver a stimulating signal to the digestive organ. One example of such a stimulator is a device configured to stimulate a stomach comprising at least one electrode coupled to the stomach and a pulse generator coupled to the electrode. Such electrodes may be implanted at the stomach, e.g., either through open surgery, laparoscopically or endoscopically.

[0043] As illustrated in Figure 12, a stimulator 120 in accordance with one example of the invention comprises a CPU 121 including a memory device 122 having lookup table 123 where stimulation parameters are associated with a random number, for example in a range of random numbers. A random number generator 124 is coupled to the CPU 121 and when prompted, randomly generates a number within a range corresponding to particular stimulation parameters. The random number generator, for example may have 100 possible random number corresponding to different parameters of a given type (e.g. 1-100 for pulse repetition rates and 101-200 for pulse widths, etc.) The random number generator may also have certain random numbers each corresponding to a particular predetermined signal to be delivered that may vary one or more parameters or may have varied shapes or types of stimulation signals.

[0044] The generated random number identifies a stimulation parameter or parameters stored in the lookup table 123 of the memory device 122. The CPU 121 then controls stimulation at the stimulation output 125 (e.g., to one or more electrodes) to deliver stimulation to a digestive organ where the stimulation corresponds to the randomly (or pseudorandomly) generated or selected stimulation parameter. More than one lookup table and random number generators may be used where multiple stimulation parameters are randomized.

[0045] Figure 10 illustrates an exemplary method and operation of a device in accordance with the invention. A random number is first generated (100) within a range of random numbers. Each random number corresponds to a particular stimulation signal or a stimulation parameter (or group of parameters) within a window or range of parameters. A pulse or burst of pulses with parameters corresponding to the generated random number is generated and delivered to a digestive organ for stimulation (101). Then a timer is started to identify when

the first signal has been initiated (102) and a random number is again generated (103) corresponding to a particular stimulation signal of a stimulation parameter (or group of parameters). And, a calculation is made as to when the next stimulation pulse or burst of pulses is to be delivered (104). The calculation of the time for delivery may depend on which stimulation parameter is being randomized. If the pulse repetition rate or burst repetition rate is the varying parameter, the calculation of when the next pulse or burst of pulses respectively is to be delivered will be based on the variation in pulse or burst repetition rate. If the pulse repetition rate or burst repetition rate is constant, the calculation of the delivery time will be constant or based on the constant pulse or burst repetition rate. If the randomization is to occur periodically, the stimulation is delivered according to a protocol with a first set of stimulation patterns until a certain period determined, e.g. by the timer, has transpired. When the period has transpired, the next randomized stimulation parameters are then used according to a stimulation protocol. If the stimulation protocol involves turning stimulation on or off under various conditions, the timer may be turned on when the stimulation is on and turned off when the stimulation is off. Alternatively, the timer may run continuously.

[0046] The time for delivery of the next signal and the time of the timer (when the previous pulse or burst of pulses began) are compared to determine if it is time for the next pulse or burst of pulses to be delivered. If it is not time to deliver the next pulse or burst of pulses (106) then the comparison is made again (105) until it is time to deliver the next pulse or burst of pulses (106) whereupon a signal with parameters corresponding to the generated random number is generated (101) and steps 102-106 are repeated.

[0047] Figure 11 illustrates a method and operation of a device in accordance with the invention. A random number for Electrode 1 is first generated (110) within a range of random numbers. A random number for Electrode 2 (111) is then generated within a range of random numbers. Each random number corresponds to a particular stimulation signal or a stimulation parameter (or group of parameters) within a window or range of parameters. A timer is then started (112) as a pulse or burst period begins. Pulses or bursts with parameters corresponding to each generated random number for Electrodes 1 and 2 are generated and delivered to a digestive organ for stimulation correspondingly at Electrodes 1 and 2 (113). These stimulation signals are independent of each other. They may, however be timed to fall within a predetermined pulse repetition rate so that generally the stimulation signals are each delivered within a preset period of time before the next set of stimulation signals are delivered to Electrodes 1 and 2. Thus, as set forth in step 112 a timer is started to identify the beginning of

a first pulse period. It is then determined if the preset time has passed (114) at which time steps 111 to 114 are repeated.

[0048] While the invention has been described with reference to certain embodiments, it will be understood that variations and modifications may be made within the scope of the following  
5 claims. Such modifications may include substituting elements or components, which perform substantially the same function in substantially the same way to achieve substantially the same result that the invention can be practiced with modification within the scope of the following claims.

WHAT IS CLAIMED IS:

- 1           1.       A digestive organ stimulator comprising:  
2           a stimulation signal generator;  
3           a signal selector coupled to the signal generator and configured to randomly or  
4 pseudorandomly select at least one signal parameter; and  
5           a stimulation output configured to be coupled to a digestive organ, wherein the  
6 stimulation generator is configured to output through the stimulation output, a stimulation  
7 signal comprising the at least one selected signal parameter.
- 1           2.       The digestive organ stimulator of claim 1 wherein the signal selector  
2 comprises a pseudorandom signal selector configured to pseudorandomly select said at least  
3 one signal parameter.
- 1           3.       The digestive organ stimulator of claim 1 wherein the at least one  
2 selected signal parameter is selected from a group comprising: pulse width, pulse repetition  
3 rate, burst frequency and burst repetition rate.
- 1           4.       The digestive organ stimulator of claim 1 wherein the at least one  
2 selected signal parameter is selected from a predetermined group of signal parameters.
- 1           5.       The digestive organ stimulator of claim 1 further comprising:  
2 a plurality of outputs wherein the signal selector is configured to select a  
3 signal parameter for each of said plurality of outputs to be delivered thereto.
- 1           6.       The device of claim 1 wherein the signal selector is configured to  
2 select a parameter for each of a plurality of parameter types.
- 1           7.       The device of claim 1 wherein the stimulation output comprises an  
2 electrode.
- 1           8.       The device of claim 1 wherein the stimulation output comprises an  
2 electrode configured to be coupled to a gastrointestinal tract.
- 1           9.       The device of claim 1 wherein the stimulation output comprises an  
2 electrode configured to be coupled to a stomach.

1           10.     The device of claim 1 further comprising a sensor configured to sense  
2 a response to stimulation of the organ wherein the sensor is coupled to the signal selector,  
3 wherein the signal selector is configured to randomly or pseudorandomly select a new  
4 parameter when the sensor does not sense an adequate response to stimulation.

1           11.     A method of stimulating a digestive organ comprising the steps of:  
2 providing a stimulator electrically coupled to the digestive organ;  
3 randomly or pseudorandomly selecting a parameter for stimulation of the  
4 digestive organ; and  
5 delivering a stimulation signal comprising the selected parameter to the  
6 digestive organ.

1           12.     The method of claim 11 wherein the step of selecting a parameter  
2 comprises pseudorandomly selecting a parameter.

1           13.     The method of claim 12 wherein the step of selecting a parameter  
2 comprises generating a random number corresponding to a parameter and determining the  
3 random parameter based on the random number.

1           14.     The method of claim 11 wherein the step of selecting a parameter  
2 comprises randomly selecting a parameter within a window of parameters.

1           15.     The method of claim 11 wherein the step of selecting a parameter  
2 comprises selecting a first parameter from a first type of parameters and selecting a second  
3 parameter from a second type of parameters; and  
4 wherein the step of delivering a stimulation signal comprises delivering a  
5 stimulation signal comprising the first parameter and the second parameter to the digestive  
6 organ.

1           16.     The method of claim 11 further comprising the steps of:  
2 sensing a response of a digestive organ to a stimulation signal;  
3 determining if the response of the digestive organ is within a desired range;  
4 and  
5 randomly or pseudorandomly selecting the new parameter if the response of  
6 the digestive organ is not within the desired range.

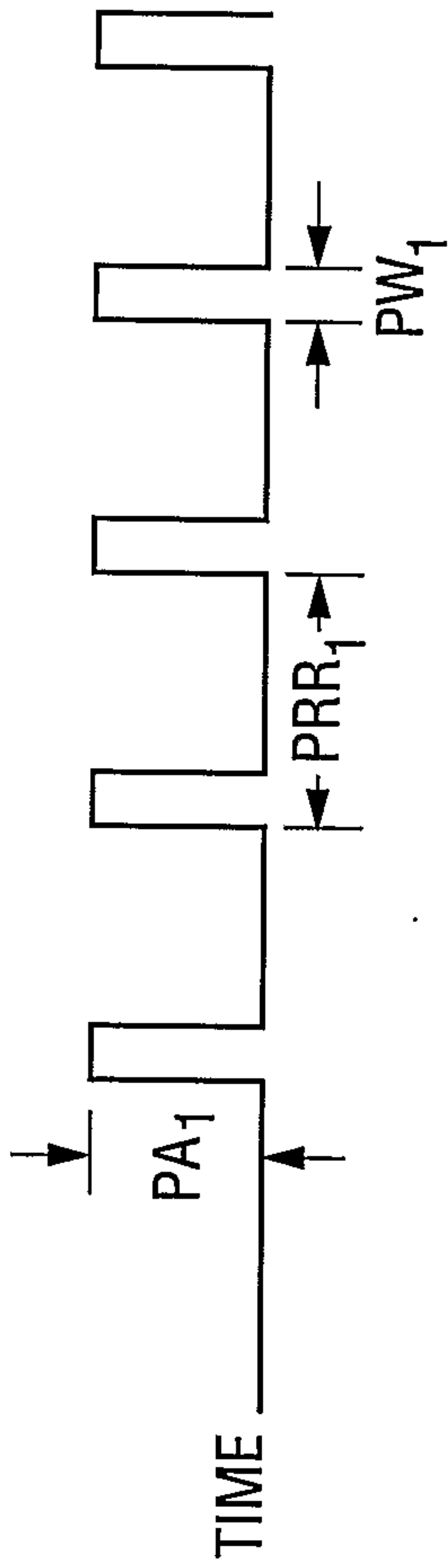
1           17.     The method of claim 11 wherein the step of delivering the signal to the  
2 digestive organ comprises delivering the signal to a portion of the gastrointestinal tract.

1           18.     The method of claim 17 wherein the step of delivering the signal to the  
2 gastrointestinal tract comprises delivering a signal to the stomach to create a sensation of  
3 satiety.

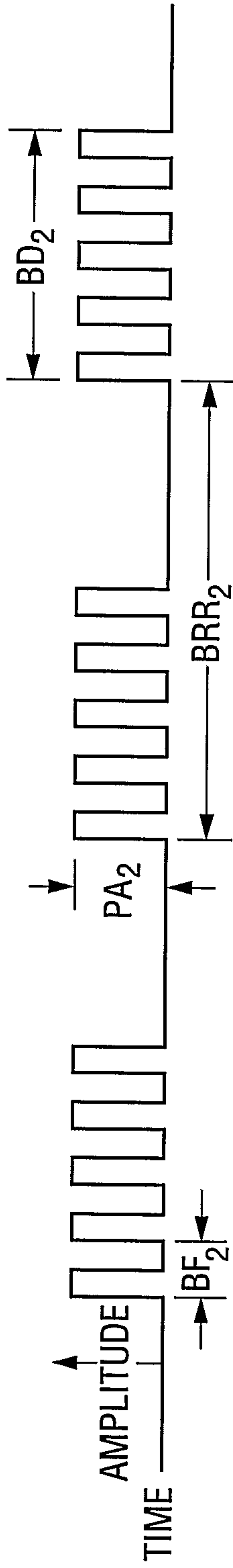
1           19.     The method of claim 11:  
2           wherein the step of providing a stimulator electrically coupled to the digestive  
3 organ comprises providing a stimulator electrically coupled to a plurality of sites at the  
4 digestive organ;

5           wherein the step of selecting a parameter for stimulation of the digestive organ  
6 comprises randomly or pseudorandomly selecting an independent parameter for stimulation  
7 at each of the plurality of sites; and

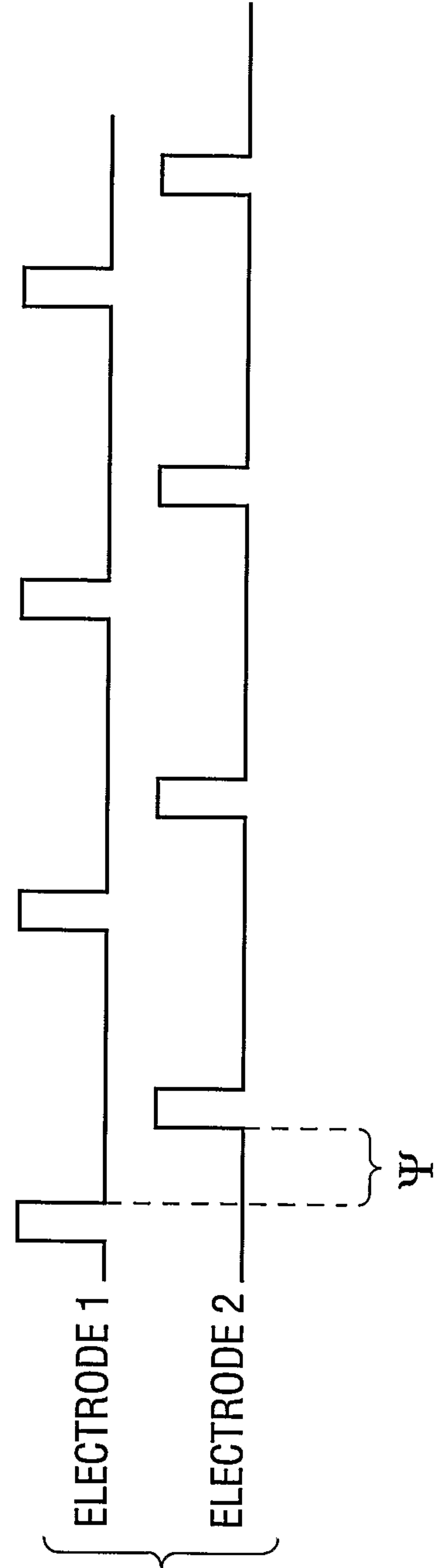
8           wherein the step of delivering a stimulation signal comprising the parameter to  
9 the digestive organ comprises delivering a stimulation signal comprising an independent  
10 parameter to each of the plurality of sites wherein the each independent parameter at a site is  
11 independently selected from other of the independent parameters delivered to other of said  
12 plurality of sites.



**FIG. 1  
(PRIOR ART)**



**FIG. 2  
(PRIOR ART)**



**FIG. 3  
(PRIOR ART)**



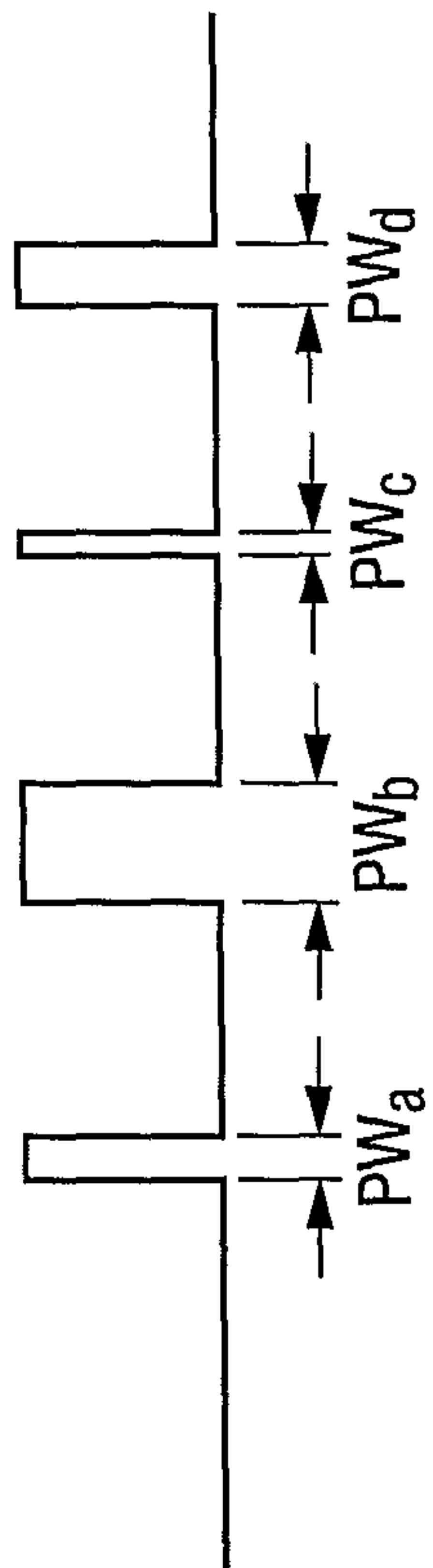


FIG. 4

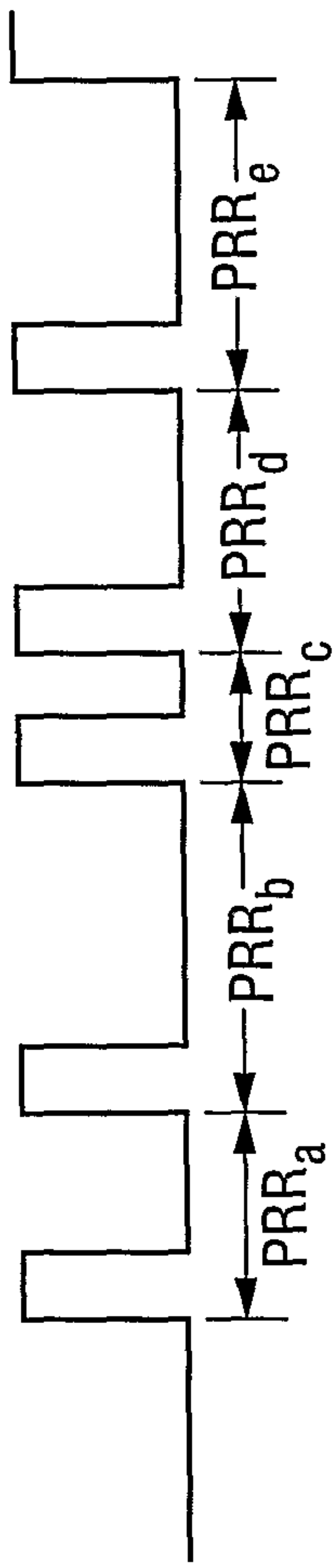


FIG. 5

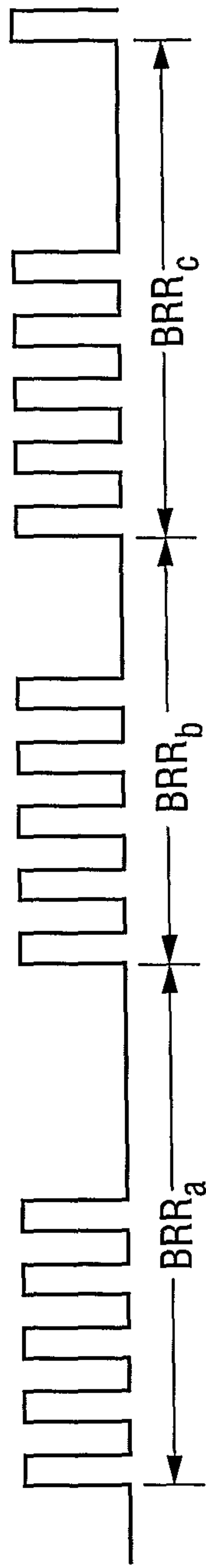


FIG. 6

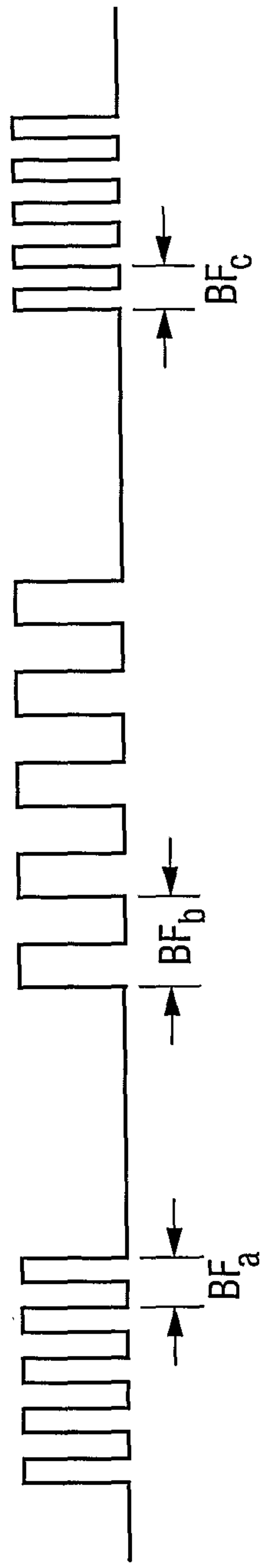
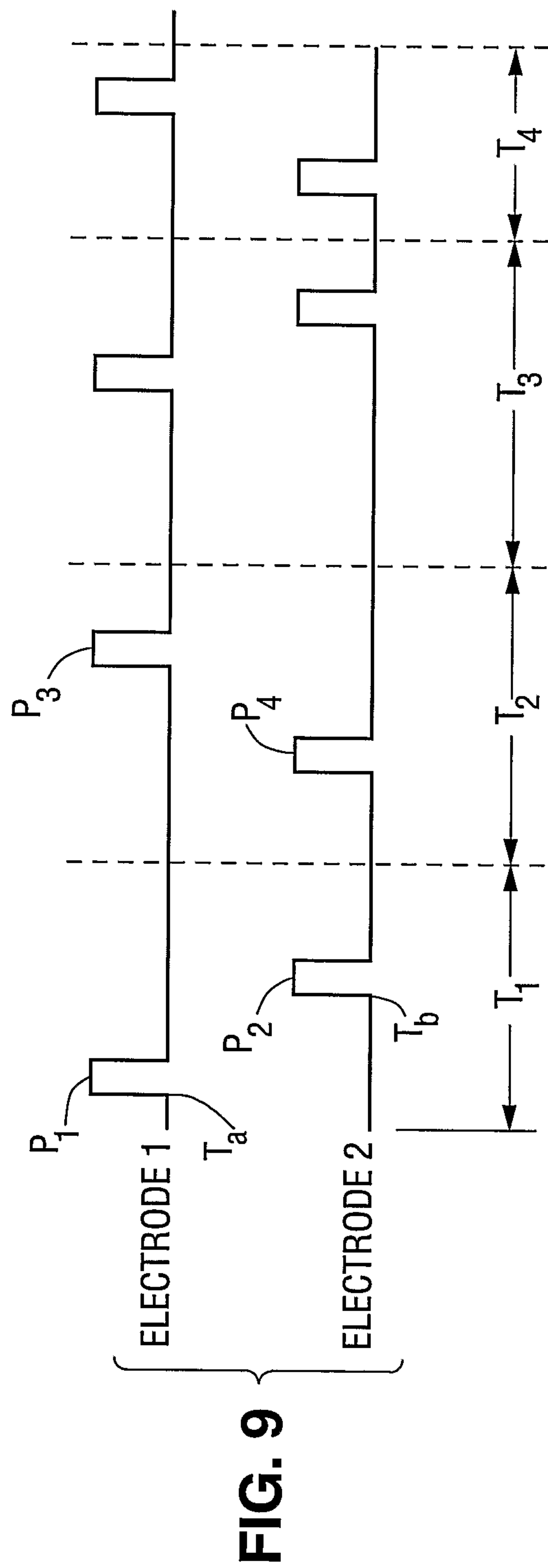
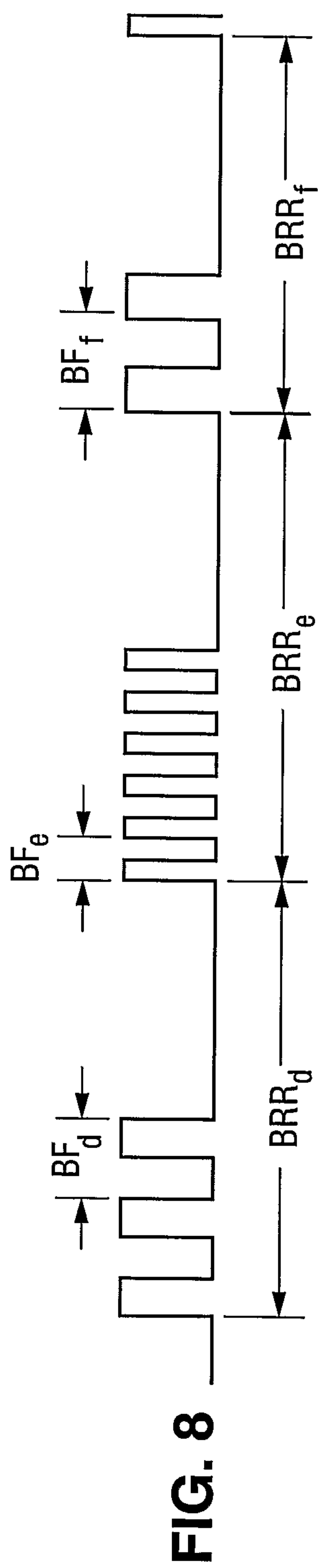


FIG. 7



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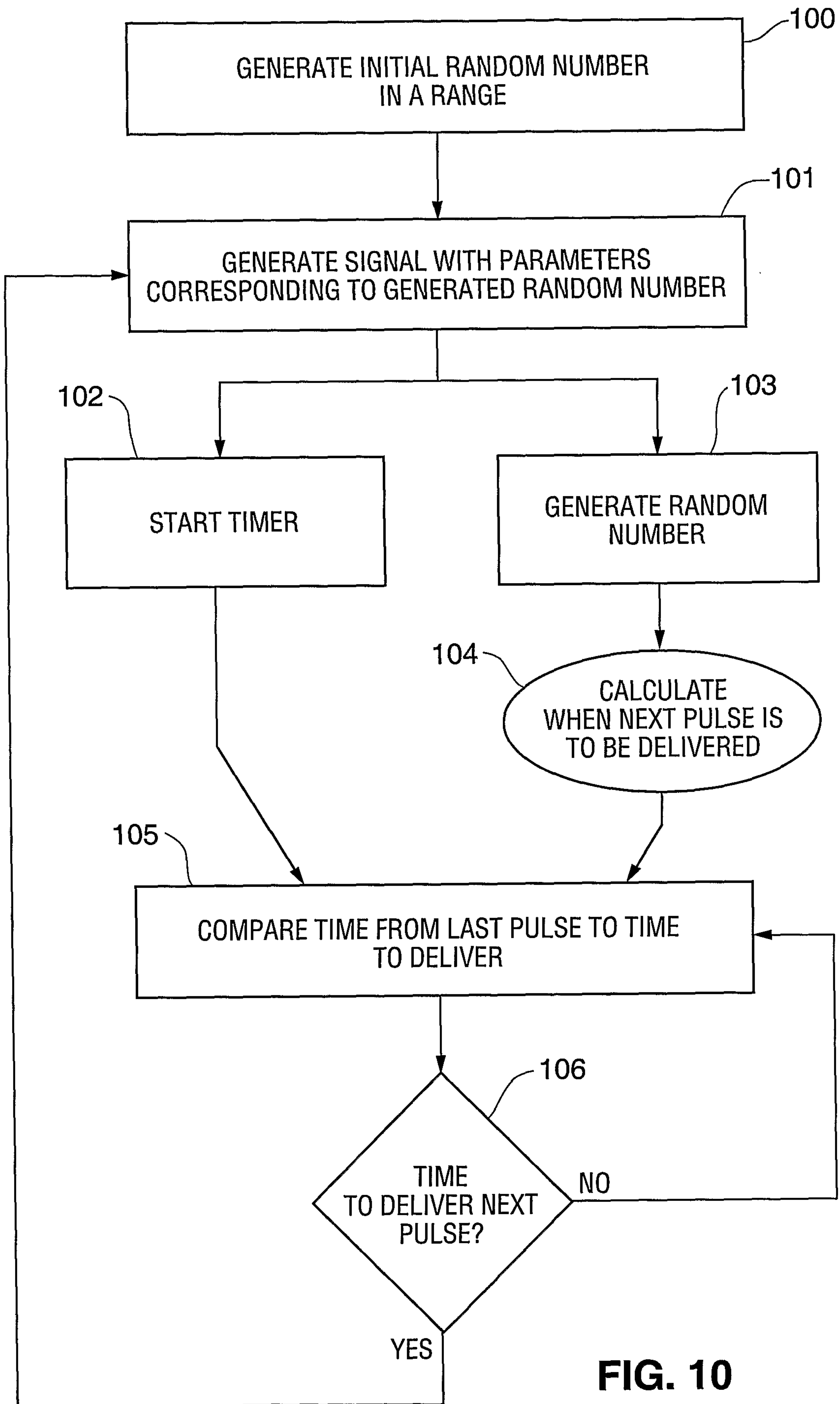


FIG. 10

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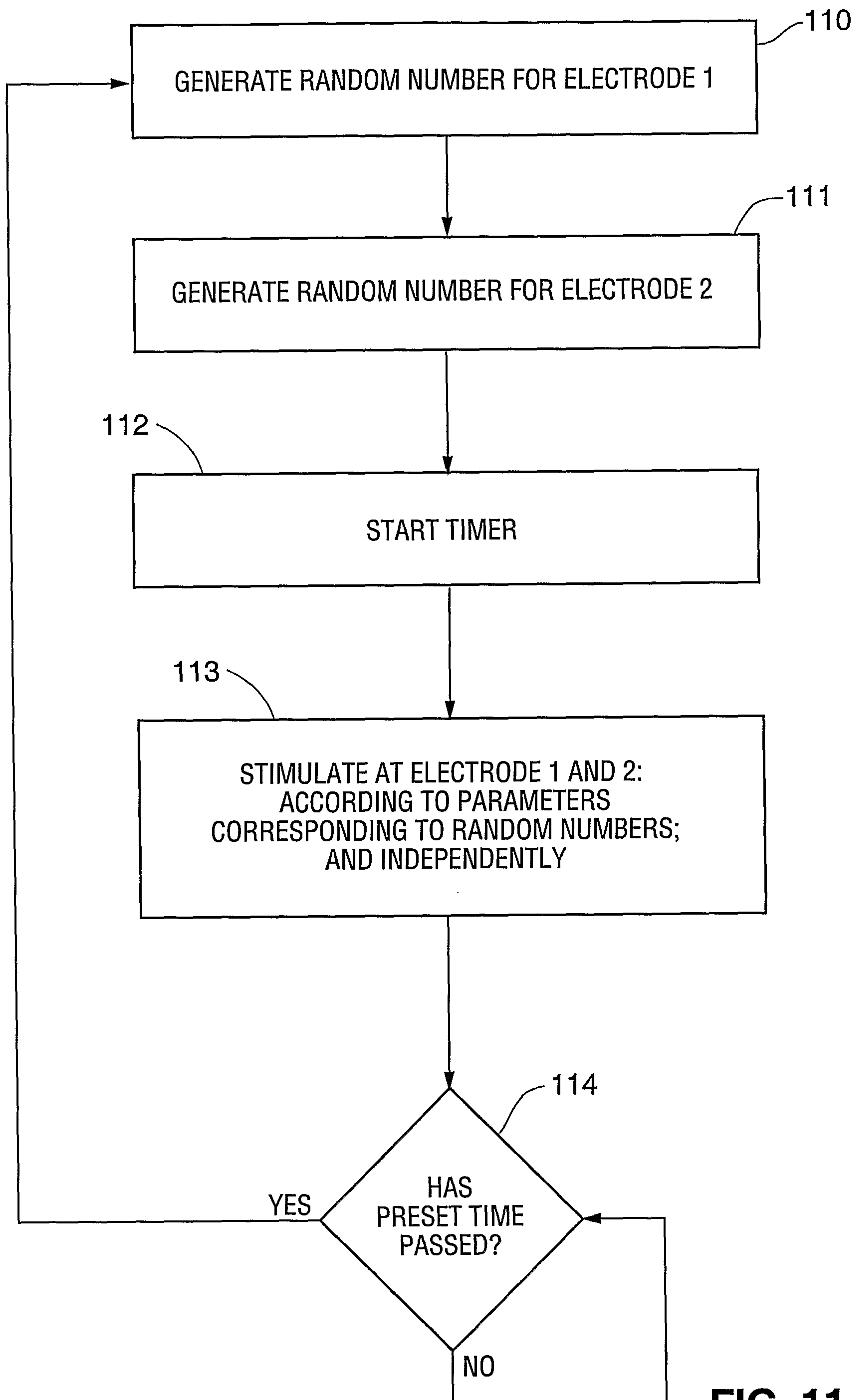


FIG. 11

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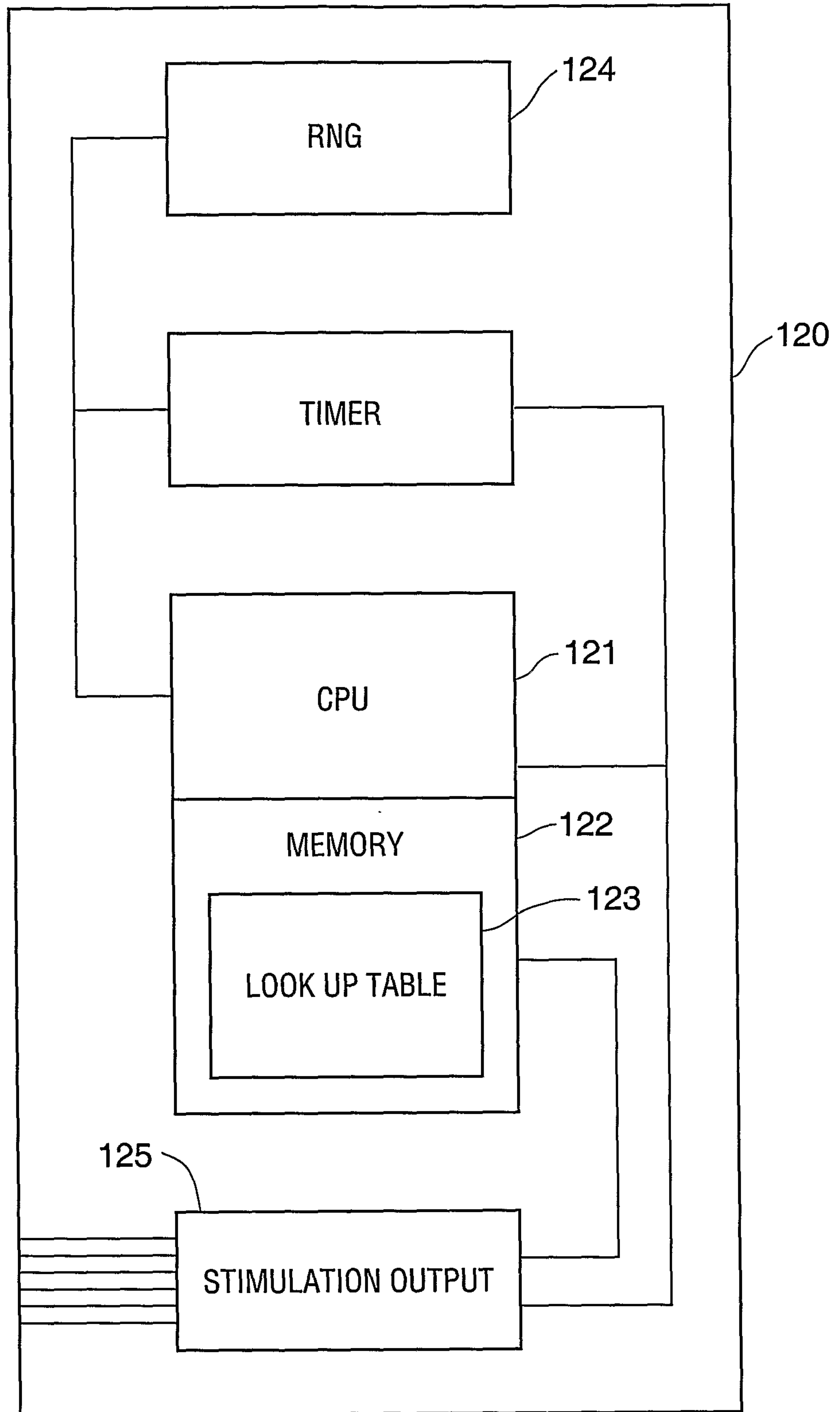


FIG. 12

