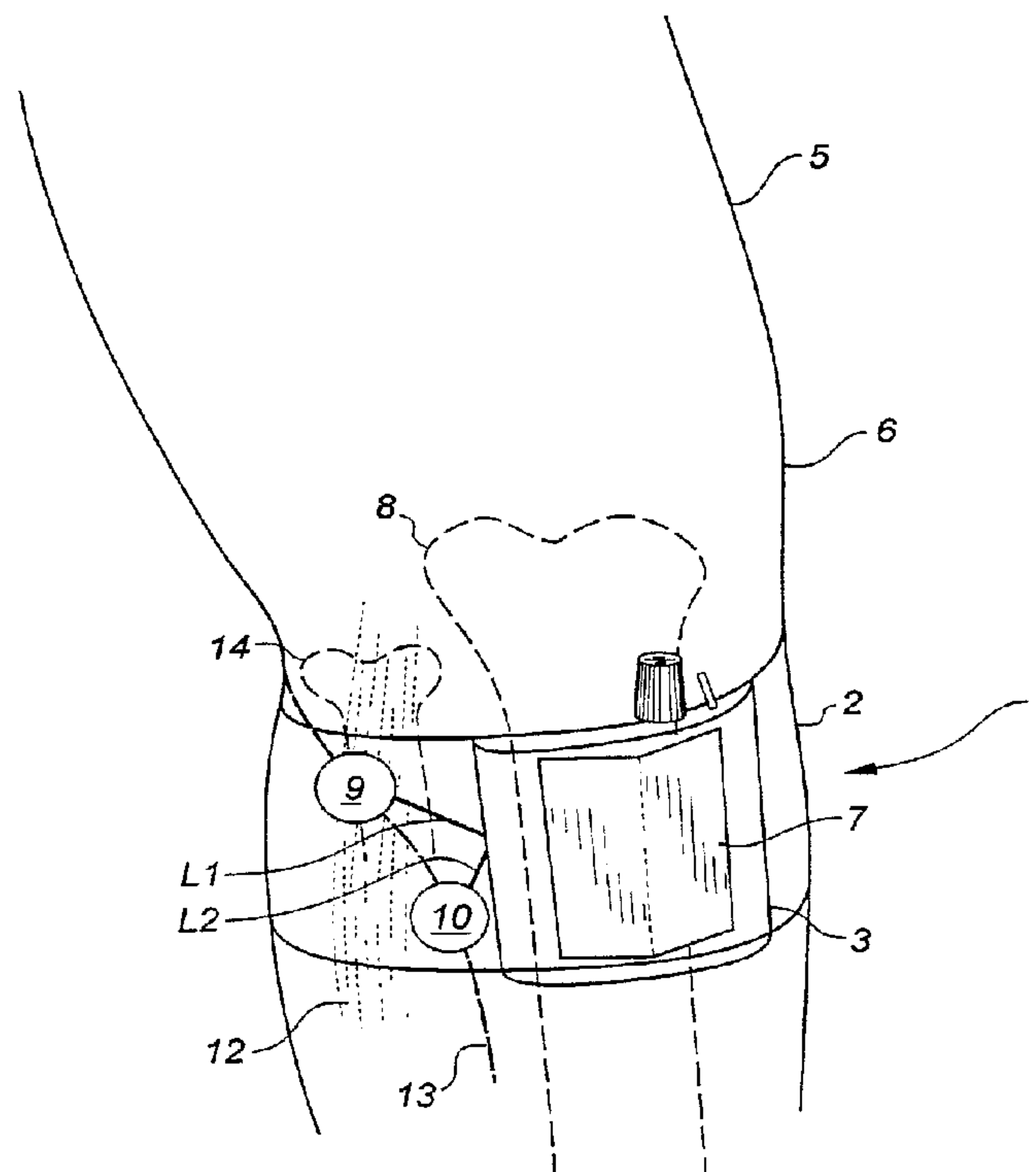




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(57) **Abrégé/Abstract:**

The assembly comprises a band, mountable on the leg, carrying all of the components of the assembly to provide a self-contained unit. The components comprise: electrodes for stimulating a leg nerve; a V-shaped plate for conforming with the leg's tibia to reproducibly position the band so that the electrodes are located over the nerve; a tilt sensor for measuring the angular position of the lower leg; a control circuit for processing the sensor signal information and emitting pulses through the electrodes to stimulate the leg in response to phases of body movement; and a battery for supplying power to the tilt sensor, control circuit and stimulator. By comparing the assembly's stimulation states against a known template defining optimal stimulation states, stimulation threshold parameters can be fine tuned without the need for repeated trial and error testing by the user.



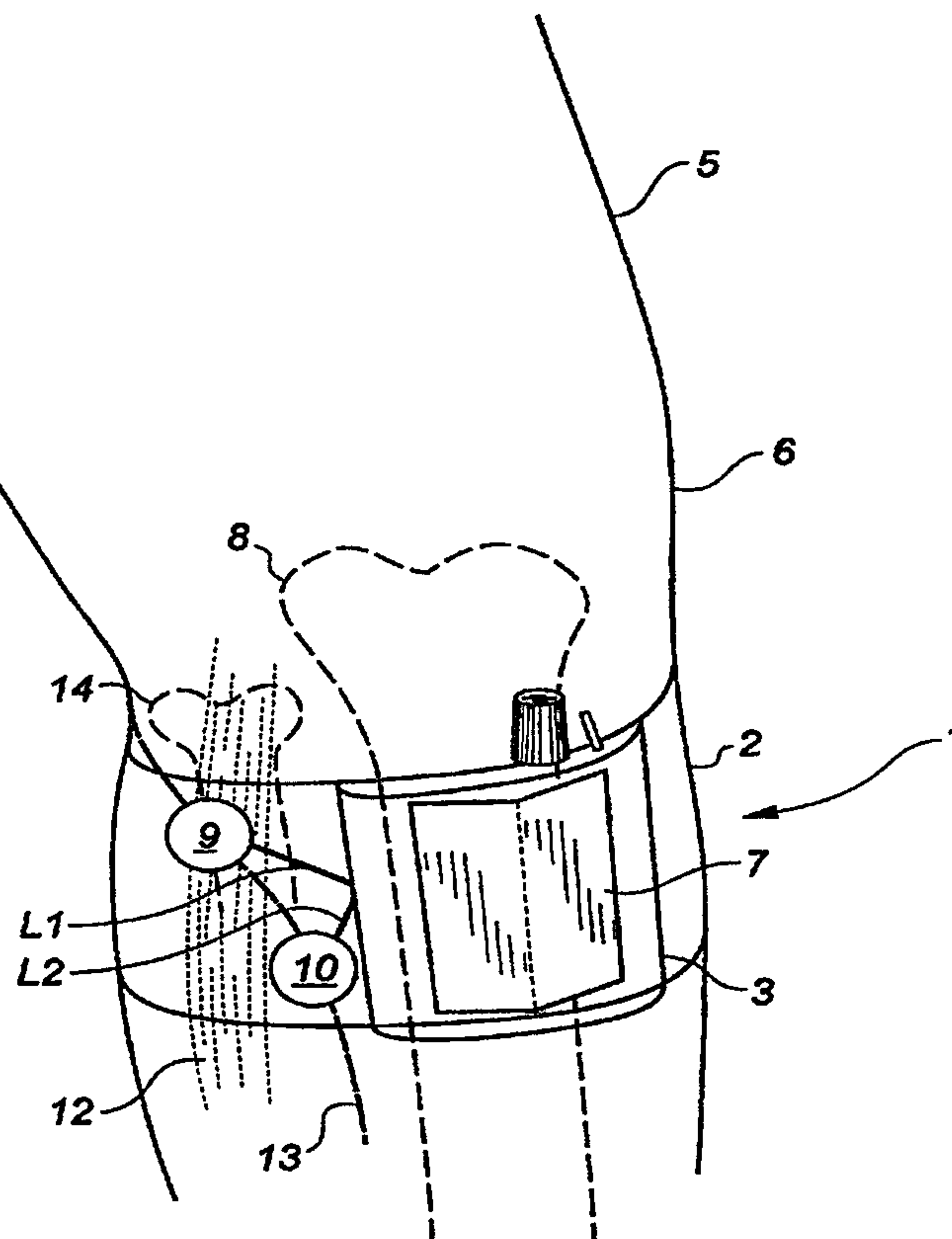
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The assembly comprises a band, mountable on the leg, carrying all of the components of the assembly to provide a self-contained unit. The components comprise: electrodes for stimulating a leg nerve; a V-shaped plate for conforming with the leg's tibia to reproducibly position the band so that the electrodes are located over the nerve; a tilt sensor for measuring the angular position of the lower leg; a control circuit for processing the sensor signal information and emitting pulses through the electrodes to stimulate the leg in response to phases of body movement; and a battery for supplying power to the tilt sensor, control circuit and stimulator. By comparing the assembly's stimulation states against a known template defining optimal stimulation states, stimulation threshold parameters can be fine tuned without the need for repeated trial and error testing by the user.



1 **ASSEMBLY FOR FUNCTIONAL ELECTRICAL**
2 **STIMULATION DURING MOVEMENT**

3 **FIELD OF THE INVENTION**

4 This invention relates to an electronic stimulator comprising a garment
5 carrying fixed electrodes and means for properly positioning the garment so that the
6 electrodes overlie a nerve to be stimulated. The garment further carries means for
7 monitoring body movement and means for activating the electrodes at appropriate
8 intervals to stimulate the nerve and activate dormant muscles, thereby assisting the
9 body in making a particular movement. For example, the stimulator may be used to
10 assist in overcoming "foot drop" affecting a person who has had a stroke.

11 **BACKGROUND OF THE INVENTION**

12 Functional electrical stimulation (FES) is a method for replacing function,
13 such as walking or grasping, that is partially or completely lost after various lesions to
14 the central nervous system, such as stroke or spinal cord injury.

15 One of the most common deficits in the lower leg is "foot drop". In this
16 condition, the patient is unable to properly activate the muscles that flex the ankle, to
17 enable the foot to clear the ground during the swing phase of walking. Instead, the
18 foot drops and drags along the ground.

19 Liberson et al, in a paper entitled "Functional Electrotherapy, Stimulation
20 of the Peroneal Nerve Synchronized with the Swing Phase of the Gait of Hemiplegic
21 Patients" Arch. Phys. Med., 1961, 42, 101-105, first proposed using electrical
22 stimulation to correct foot drop. The authors suggested that the stimulation be
23 controlled by a heel sensor. When the person leaned forward and reduced heel
24 pressure, switch contacts built into the shoe heel would open. Upon opening the

1 switch, current would flow to electrodes positioned over the common peroneal nerve
2 near the knee. The nerve would be stimulated and innervate muscles that flex the
3 ankle. Upon muscle contraction, the foot would flex and clear the ground without
4 dragging during swing. When the heel returned to the ground at the beginning of
5 stance phase, the switch contacts would close and stimulation would be terminated.

6 A number of variants of the basic system have been tried over the years
7 and some success has been attained. The commonly known prior art electronic
8 stimulators are reviewed in an article by Kralj et al, "Enhancement of Hemiplegic
9 Patient Rehabilitation by Means of Functional Electrical Stimulation; Prosthet. Orthot.
10 Int., 1993, 17, 107-114.

11 However, the most common device fitted for people with the condition
12 of foot drop is still an ankle-foot orthosis ("AFO"). An AFO does not involve electrical
13 stimulation. It is a plastic brace that fits around the lower leg and holds the foot fixed,
14 usually at an angle near 90° with respect to the long axis of the leg.

15 Although AFO's have several disadvantages, the electrical stimulators
16 have not significantly replaced them because the latter have a number of drawbacks.
17 Included among these drawbacks are:

- 18 1. that the electrical stimulators comprise a number of pieces, all of
19 which have to be placed and connected together accurately.
20 Carrying this out is a difficult and time-consuming chore for a
21 patient who has likely lost some manual dexterity and who may
22 have suffered some cognitive impairment as a result of stroke or
23 injury. More specifically, these stimulator units typically comprise:
24 (a) a box containing the stimulator, battery and control

1 Electronics, which have to be placed on the body or in a pocket;
2 (b) electrodes which have to be placed accurately on the skin;
3 (c) some garment, such as an elastic knee stocking, for
4 supporting the electrodes in place; (d) a foot switch; and (e)
5 wiring connecting the electronics and electrodes;

6 2. that the lengthy wiring is prone to breakage;

7 3. that the foot switch may not work reliably on all of several
8 different surfaces such as pavement, carpet, sand, up and down
9 ramps and the like; and

10 4. that some patients may not land on their heel or put little weight
11 on it, due to spasticity or contractures in the calf muscles.

12 These problems can lead to failure to trigger the stimulation. An
13 alternative is to have a fixed duration of stimulation. This may
14 be appropriate at some speeds of walking or levels of fatigue,
15 but not at others.

16 Another prior art reference of interest is PCT application WO95/10323.
17 This publication teaches a glove having a stimulation assembly for activating
18 muscles of the hand. More particularly it describes a functional electrical
19 stimulator, for use on a human limb, comprising a garment carrying the
20 stimulator components including electrodes for emitting pulses to stimulate
21 the limb, sensor means for monitoring movement of the limb and emitting
22 signals indicative thereof, control circuit means for processing the signals and
23 initiating and terminating stimulation at appropriate times for appropriate
24 periods, and battery means for supplying electrical power to the components.

25 With this background in mind, I set out to design an electronic
26 stimulator which is easy to don and doff, which automatically and accurately
27 positions the electrodes, which incorporates sensors that more completely
28 monitor body motion and do not require heel pressure, which uses relatively
29 short connecting wires, and which controls stimulation in response to the
30 stage of body motion.

1 In developing the invention, I have used a locating means disclosed in
2 United States patent 4,381,012, issued to Russek. This patent teaches a garment
3 carrying a member which closely conforms to the protuberance of the spine. By
4 positioning the member over the spine, electrodes carried by the garment are
5 automatically located accurately over nerves to be stimulated.

6 7 SUMMARY OF THE INVENTION

8 In a first aspect, a stimulator in accordance with a preferred form of the
9 present invention comprises, in combination:

- 10 • a band of stretchable, breathable fabric having fastening means at
11 its ends for securement of the band around the user's leg in the
12 form of a ring;
- 13 • anode and cathode electrodes carried by the band in a stationary
14 or fixed condition;
- 15 • locating means, carried by the band, for cooperating with the bony
16 protuberance of the tibia, to accurately and reproducibly locate the
17 electrodes over the nerve to be stimulated;
- 18 • tilt sensor means, carried by the band, for measuring the angle of
19 the lower segment of the leg relative to vertical in the sagittal
20 (forward and back) plane and emitting sensor signals indicative
21 thereof;
- 22 • battery means, carried by the band, for supplying electrical current,
23 as required; and

- 1 • control means, carried by the band and connected with the
2 sensor means, electrodes and battery means, for receiving the
3 sensor signals, processing the sensor signals to establish values
4 indicative of the changing angularity of the limb (that is, position
5 of the lower leg with respect to vertical) and to compare the
6 established values with predetermined adjustable ON and OFF
7 threshold values and initiating and terminating emission of
8 electrical pulses through the electrodes on respectively reaching
9 the ON and OFF threshold values to stimulate the leg muscles in
10 response to phases of body movement.

11 The band, carrying the components, is compact and thin enough to fit
12 comfortably under pants or other clothing.

13 The combination of the locating means and fastening means has enabled
14 the assembly to be easily donned with the electrodes correctly located, even when
15 handled by an impaired user. Test trials have shown that the entire assembly can be
16 donned or doffed in less than a minute.

17 The combination of the tilt sensor with the control means provides a fine
18 degree of continuous leg position monitoring coupled with accurately initiated and
19 terminated stimulation. The result is that stimulation can be closely related to leg
20 position to provide an improved and refined pattern of stimulation, in comparison to
21 prior art FES units. The device provides continuous sensory signals and turns the
22 stimulus on and off regardless of the speed of walking.

1 Those skilled in the art will realize that certain of the components
2 described can be replaced with equivalents. For example, a resilient C-
3 shaped carrier could replace the band. Another sensor, such as an
4 accelerometer or electric compass, could be substituted for the tilt sensor.

5 However, the disclosed components are preferred. The elastic band
6 provides good securement and is easily donned and doffed. The tilt sensor
7 provides accurate information even though the user is fat or thin, walks with
8 shoes or in bare feet and walks fast or slow on a variety of surfaces having
9 different inclinations. The tilt sensor further is less sensitive to pathological
10 changes such as contractures or clonus at the ankle, than is the case for a
11 heel switch.

12 Broadly stated, the invention is a functional electrical stimulator, for use
13 on a human limb, comprising a garment carrying the stimulator components
14 including electrodes for emitting pulses to stimulate the limb, sensor means
15 for monitoring movement of the limb and emitting signals indicative thereof,
16 control circuit means for processing the signals and initiating and terminating
17 stimulation at appropriate times for appropriate periods, and battery means for
18 supplying electrical power to the components, characterized in that: the
19 stimulator (1) is for use on a leg; the garment is a band (2), mountable on the
20 leg; cathode and anode electrodes (9, 10) are carried by the band in a fixed
21 condition; means (7) are carried by the band for reproducibly positioning the
22 band so that the electrodes are located at specified stimulation locations;
23 sensor means (17) are carried by the band in a fixed condition, for measuring
24 the angular position of the leg during movement and emitting sensor signals
25 indicative thereof; control circuit means (19, 20) are carried by the band and
26 are connected with the sensor means and electrodes, for receiving the sensor
27 signals, processing the sensor signals to establish values indicative of the
28 changing angularity of the leg, comparing the established values with
29 predetermined adjustable angular ON and OFF threshold values and initiating
30 and terminating the emission of pulses through the electrodes when the
31 established values reached the ON and OFF threshold values, to stimulate
32 the leg; and the battery means (18) are carried by the band and are
33 connected with the sensor means and control circuit means, for supplying
34 electrical power to them.

1 In some instances it is preferable to also compare the established
2 values with predetermined adjustable maximum time thresholds and terminate
3 limb stimulation should they be exceeded.

4 In another aspect of the invention, a patient using the apparatus in
5 combination with a clinician or other means, can generate the data necessary
6 to better define the parameters such as angular ON and OFF threshold values
7 and time thresholds. In a preferred aspect, a hand switch, operated by a
8 clinician, or a limb mounted sensor is used to define the states at which
9 stimulation of the limb is required for proper limb movement. In other words a
10 template is defined for optimal stimulation of the limb. By comparing the limb
11 stimulation states which are actually output by the apparatus and those
12 defined by the template, the parameters used by the apparatus stimulator
13 control circuits can be optimized.

14 DESCRIPTION OF THE DRAWINGS

15
16 Figure 1 is a schematic showing the stimulator mounted on a leg with
17 the locations of the tibia and common peroneal nerve shown in dotted lines;

18 Figure 2 is a perspective view showing the stimulator with the pouch
19 wall broken away to display the tilt sensor, battery and circuit boards;

20 Figure 3 is a top view of the system, showing connections between the
21 logic circuitry, tilt sensor, battery, stimulator circuits and the electrodes;

22 Figure 4 is a block diagram showing the tilt sensor, logic, power and
23 stimulator circuits and the electrodes;

1 Figure 5 is a diagram showing the operation of the logic circuitry in
2 conjunction with data recorded from a patient user; and

3 Figures 6 and 7 are diagrams showing the operation of the logic circuitry
4 for data recorded from a patient according to original parameters (Figure 6) and
5 optimized parameters (Figure 7) as they relate to the Example.

6 DESCRIPTION OF THE PREFERRED EMBODIMENT

7 Having reference to Figures 1 and 2, the stimulator 1, comprises a band
8 2 made of stretchable, breathable material. One suitable material is perforated
9 neoprene, available from Rubatex Corporation, Bedford, VA. The band 2 forms a
10 pouch 3, for containing stimulator components. Patches 4 of Velcro* fastening
11 material are provided at the band ends to fasten them together, so that the band can
12 form a snug ring around the user's leg 5 below the knee 6.

13 A V-shaped metal plate 7 is positioned in the pouch 3 and fits snugly
14 therein so as to be fixed along the length of the band. The plate 7 is weakened along
15 its vertical mid-line. It can be readily bent therealong to conform to the anterior
16 position of the tibia 8. The plate may include vertical protrusions which lay parallel to
17 and on opposing sides of the tibia to more positively constrain lateral movement
18 relative to the tibia. Once so bent, the plate 7 can be located reproducibly on the tibia.

19 Cathode and anode electrodes 9, 10 are attached to the band 2 with
20 conductive snap connectors 11 as shown in Figure 3.

21 *Trade Mark

1 The optimal placement of the electrodes 9, 10 is determined by a
2 technician or clinician working with the patient. The cathode electrode 9 is usually
3 placed where the common peroneal nerve 13 comes from behind the knee 6 past the
4 head of the fibula 14. Placement of the anode electrode 10 is less critical. It is
5 usually placed further along the course of the nerve 13, where it enters the ankle
6 flexor muscles 12. Once these locations are determined, the band 2 is placed over
7 the electrodes and holes are punched through the fabric with a hole punch. The
8 electrodes contain a male connector that is fitted through the hole and connected with
9 the female connector 11. These female connectors are attached to leads L1, L2.

10 The electrodes used are of the water-filled cotton type, available from the
11 Josef Stefan Institute, Ljubljana, Slovenia.

12 In summary then, the band 2 is reproducibly positioned by fitting the plate
13 7 over the tibia 8, thereby locating the electrodes 9, 10 at the desired positions.

14 A tilt sensor 17 (otherwise known as an inclinometer) is secured to a
15 printed circuit board containing logic circuit 19 which in turn is attached to the
16 positioning plate 7. Thus, the tilt sensor is fixed with respect to the tibia and the rest
17 of the lower leg. As previously stated, the tilt sensor 17 functions to measure the
18 angle of the lower leg with respect to the vertical in the sagittal plane and emit signals
19 indicative thereof. One suitable sensor for this purpose is available from Midori Inc.
20 Fullerton, CA, under the designation Model No. UV1.

1 A 1.5 V AA alkaline or 1.2 V AA NiCd battery 18 for powering the
2 components is attached to the plate 7. The output voltage of the battery 18 is
3 increased to 3 volts by a DC-DC converter 28, for operation of the logic circuit 19. As
4 described below, the battery output voltage is increased through a second converter
5 (not shown) to 5 V and further then to 70 volts by a transformer 29, for operation of
6 the stimulator circuit 20.

7 The logic circuit 19 and stimulator circuit 20 are mounted to the plate 7
8 and together comprise control circuit means.

9 The logic circuit 19 functions to receive the tilt sensor signals, condition
10 them, compare them to threshold values related to changes in gait and to activate or
11 de-activate the stimulator circuit 20 in response thereto.

12 As shown in Figures 3 and 4, the logic circuit 19 is connected by suitable
13 leads L3 - L6 with the battery 19, tilt sensor 17 and stimulator circuit 20.

14 For simplicity, lead L3 from the DC-DC converter is only shown
15 connected to the comparator and filter circuits in Figure 4, but in reality it powers all
16 elements on the logic circuit board 19.

17 The transformer 29 functions to increase the low voltage battery to higher
18 voltage and the stimulation circuit 20 produces short energy pulses. It is connected
19 with the electrodes 9, 10 by leads L1 and L2.

20 The components and functions of the logic circuit 19 are now described.

1 The tilt sensor 17 produces an analog sensor signal of varying voltage,
2 dependent on its angular position relative to gravity. This sensor signal is transmitted
3 to the filter circuit 21 through lead L7. The signal is filtered by a standard R.C. filter
4 circuit 21. It has values of: $R = 82 \text{ Kohms}$, $C = 1.0 \mu\text{F}$. The filter R.C. circuit 21
5 removes the higher frequency acceleration signals.

6 The filtered sensor signal is then amplified by operational amplifier 22.
7 The amplifier used is available from Texas Instruments under designation TLC 274.
8 The amplifier 22 increases the output voltage by 10 to 20 times.

9 The amplified sensor signal is then filtered by a second R.C. filter circuit
10 23, which has values of $R = 82 \text{ Kohms}$ and $C = 1.0 \mu\text{F}$. Together the circuits 21 and
11 23 comprise a second-order low-pass R.C. filter with a cutoff frequency of 2 Hz.

12 The filtered, amplified (i.e. "conditioned") sensor signal is transmitted
13 from filter R.C. circuit 23 to comparator circuit 24. The signal is an analog one,
14 delivered in volts. The comparator circuit 24 signals activation or deactivation of the
15 stimulator circuit by emitting a digital control signal via lead L6. The comparator circuit
16 used is available from Texas Instruments under the designation TLC 274.

17 The comparator circuit 24 compares the conditioned sensor signal
18 voltage with an angular ON threshold and operates to activate the stimulator circuit
19 when the threshold is exceeded. A potentiometer 25 enables adjustment of the
20 angular ON threshold. The potentiometer used is available from R. S. Components
21 Ltd., Corby, Northants., U.K., under the designation 186-974.

1 The comparator circuit 24 also compares the conditioned sensor signal
2 voltage with an angular OFF threshold and operates to deactivate or turn off the
3 stimulator circuit 20 if the voltage drops below this threshold. Potentiometer 30 (also
4 available from R. S. Components) provides a variable amount of hysteresis. In other
5 words, the angular OFF threshold will differ from the ON signal by an amount between
6 0 and 0.5 volts, depending on the setting of the potentiometer 30.

7 Thus, the comparator circuit 24 emits a HI control signal (3 volts) when
8 the conditioned sensor signal voltage becomes greater than the angular ON voltage
9 (ON threshold) and a LOW control signal (0 volts) when the voltage becomes less
10 than the angular OFF voltage (OFF threshold).

11 The digital control signal is delivered via L6 to a timer circuit 26 (the
12 function of which is described below) and thereafter to a lock-out circuit 27. Once the
13 control signal is gated LOW (stimulation to be deactivated), there is a further time,
14 referred to as the lock-out period, during which the lock-out circuit, via lead L5,
15 prevents re-activation of the stimulus. The lock-out circuit used is available from
16 Motorola Semiconductor Products Inc., Austin TX under designation CD4538. Lock-
17 out normally occurs at about the time that the heel strikes the ground (see Figure 5),
18 which gives rise to some oscillation (known as "clonus"). During clonus, even if the
19 conditioned signal were to reach the angular ON threshold, the lock-out circuit 27
20 functions to continue to gate the comparator output LOW to prevent premature re-
21 triggering of the stimulator circuit 20. The lock-out time can be adjusted between 0.1
22 and 1 second, using the potentiometer 32 (available from R. S Components).

1 Thus, the comparator and lock-out circuits 24, 27 monitor the digital
2 control signals and the comparator delivers a HI or a LOW digital signal, as
3 appropriate, to the stimulator circuit 20. More particularly, the comparator circuit 24
4 delivers a HI signal to the stimulator circuit to turn stimulation ON. The comparator
5 circuit delivers a LOW signal to turn the stimulation OFF. The OFF or LOW signal is
6 processed through the lock-out circuit to introduce the appropriate delay.

7 In some instances during walking, the patient's leg may not exhibit an
8 angular OFF control signal which occurs early enough in time to properly deactivate
9 the stimulator circuit 20. Therefore, in an alternate embodiment, the stimulator circuit
10 may be deactivated by measuring the time which has elapsed, since the comparator
11 24 first signalled activation of the stimulation circuit, and comparing it against a
12 maximum elapsed time threshold.

13 More particularly, the timer circuit 26 is configured to allow adjustment
14 of the maximum allowable elapsed time from 0.2 seconds to 4 seconds using
15 potentiometer 31 (available from R. S. Components). The timer circuit used is
16 available from Motorola under designation CD4538.

17 If the conditioned signal voltage does not go below the angular OFF
18 threshold before reaching the maximum time threshold set by timer circuit 26, the
19 comparator circuit 24 digital HI signal is gated LOW, signalling deactivation of the
20 stimulator circuit 20, subject of course to the lock-out circuit 27.

21 Thus, each of the parameters - angular ON and OFF thresholds,
22 maximum time threshold and lock-out period - are adjustable through the
23 potentiometers 25, 30, 31, and 32 respectively.

1 A socket 33 is provided in the design so that the signals can be brought
2 from the logic circuit to a digital computer for ease of adjusting the potentiometers and
3 sensor data, as described later. Another socket 37 is also provided for connecting a
4 hand or foot switch, should some patients be unable to use a tilt sensor due to the
5 inability to generate sufficient tilt of the lower leg. The circuitry for processing these
6 signals is not novel and is not detailed in Figure 4. Essentially, inserting a hand or
7 foot switch into the jack disables the filter and amplifier circuits and the alternative
8 devices are connected directly to the comparator circuit 24. A choice of sensors
9 provides flexibility to the preferred design.

10 The stimulator circuit 20 receives the digital control signal and delivers
11 a series of stimuli (approximately 0.3 ms pulses at 40 ms intervals) through the
12 electrodes 9, 10 for a period when the control signal remains HI. Also shown in Figure
13 2 are an amplitude control 34 for adjusting the strength of the stimulus (0 - 100 mA)
14 and a switch 35 for turning the stimulator and logic circuitry on and off. A suitable
15 stimulator circuit, for this purpose, is available from Institute Josef Stefan under
16 designation Mikrofes Stimulator.

17 Reliable operation, even for persons whose movement is weak or who
18 have considerable clonus (oscillation), is obtained as shown in Figure 5. This Figure
19 illustrates two complete step cycles of a person using the device described in the
20 embodiment above. The conditional tilt signal (after amplification and filtering) is
21 illustrated by the solid line in the top part of the Figure. It increases as the body
22 rotates over the leg, while the leg is on the ground during the stance phase of the step
23 cycle. When the leg is behind the body, the angular ON threshold is exceeded
24 (ON_TH. in Figure 5) and stimulation begins. Stimulation continues until 1) the tilt

1 signal falls below the angular OFF threshold (OFF_TH. in Figure 5), as the leg is
2 brought in front of the body during the swing phase of the step cycle, or 2) the
3 maximum time threshold set by the timer circuit 26 is exceeded (not occurring in
4 Figure 5). The lockout circuit 27 prevents a subsequent re-triggering of the stimulation
5 for a period of time, even if oscillations in the tilt signal reach the angular ON threshold
6 (point A). The presence of hysteresis (the difference between the angular ON and
7 OFF thresholds) prevents the stimulus from turning off prematurely should the stimulus
8 happen to fall below the angular ON threshold, but not below the OFF threshold (point
9 B).

10 Determination of stimulation requirements for proper limb movement is
11 dependent, in part, upon the nature of the person's disability, the clarity of the signals
12 received and differing physiological conditions such as walking speed and terrain.
13 Accordingly, to avoid subjecting a patient to repeated trial and error testing, it may be
14 necessary to adjust several control circuit parameters which affect initiation and
15 termination of limb stimulation, including angular ON and OFF thresholds and time
16 thresholds such as maximum stimulation time and lockout time.

17 Set-points for stimulus initiation and termination can be represented by
18 a template which define the state of stimulation as being either ON or OFF, as a
19 function of angle and time. By comparing the state of the stimulator circuit control
20 output against the template, performance can be assessed and optimal adjustment for
21 the control parameter settings can be predicted.

1 One such template is defined by a trained clinician who, by observing the
2 gait of a patient and using a hand on/off switch, signals when stimulus should
3 optimally be in an ON or OFF state. Alternately, a foot switch or one or more foot
4 sensors can be temporarily employed during testing.

5 A foot switch produces either an ON or an OFF signal and indicates
6 when the foot lifts from the ground and subsequently strikes the ground. A foot sensor
7 produces a continuous and variable analog signal proportional to a foot's force against
8 the ground. As a result, the position of the foot is somewhat less certain. By
9 specifying a signal threshold, the signal can be analyzed to convert it to a binary
10 ON/OFF or HI/LOW signal. More specifically, the threshold is set so that the signal
11 is HI when the foot leaves the ground (force is lower than the threshold). The signal
12 is set to LOW when the foot is lowered on to the ground and the signal falls below the
13 threshold (force is greater than the threshold).

14 Once it has been determined that the foot is on or off of the ground, it
15 must be established whether stimulation should be ON or OFF. Optimally, stimulation
16 occurs a short time after the foot's heel leaves the ground and is terminated a short
17 time after the heel strikes the ground. Thus, a template patterned after a foot switch
18 or sensor would incorporate appropriate time delays.

19 The optimal state of stimulation, defined either by a hand switch or foot
20 switch, is stored by a digital computer for subsequent analysis.

The ON or OFF state of the limb stimulation, as established by a hand switch or foot switch template is compared with that produced by the stimulator circuit for a stored set of tilt sensor test data, from a trial, comprising a plurality of step cycles. As shown in Table 1 below, four conditions are possible; an "error" representing that situation where the active circuit-generated state is inconsistent with the template-predicted state.

Table 1

	TEMPLATE	STIMULATOR output	ERROR
1)	ON	ON	correct
2)	ON	OFF	incorrect
3)	OFF	ON	incorrect
4)	OFF	OFF	correct

The results are optimal when the percentage of recorded data in which the incorrect stimulation occurs during the trial (conditions 2 and 3) is minimized.

The stimulus ON and OFF signal is responsive to a multiplicity of parameters, four of which are: ON and OFF thresholds based on tilt angle; maximal permitted time of stimulation (maximum time OFF threshold); and lockout time at heel strike.

It is conceivable that variations in these four and other parameters can be made to improve or optimize the stimulator circuit performance as compared to the template.

1 One approach to optimize multiple parameters is to apply a gradient-
2 search technique. An error value is calculated as being the percentage of data
3 samples having incorrect stimulation over the total number of samples for the set. The
4 optimization approach is then applied to minimize the error value for a set of step
5 cycles deemed representative of the person's gait.

6 A gradient-search basically varies the value of one parameter at a time
7 and observes its effect on the error, seeking the greatest decrease (steepest descent)
8 in error. When all parameters have been varied, without further decrease in error, the
9 step size or magnitude of the variation is reduced and the process is repeated.
10 Generally, the gradient-search optimization is performed as follows:

- 11 • obtain and store a set of data samples for the patient comprising
12 a plurality of uniform step cycles;
- 13 • establish the initial magnitude of variation to be applied to each
14 parameter, being typically 1/2 or 50 % of the difference between
15 the current value of the parameter and its maximal range or value
16 experienced in the set of data samples;
- 17 • starting with the parameters that were last used (ie. the settings
18 used during the patient's trials), vary each parameter by the
19 magnitude of its variation, apply it to the data and re-calculate the
20 error (try both increasing and decreasing the value);
- 21 • If the error is successfully decreased, then that new value for the
22 parameter which produced the greatest reduction in the error is
23 substituted;
- 24 • repeat the process until the error cannot be reduced further; and

- 1 • reduce the magnitude of the variation applied to each parameter
2 by 1/2 and repeat the above. Typically, once the magnitude of
3 the variation has been reduced to about 1 %, no further
4 significant optimization of the error is apparent.

5 The optimized parameters are then input at the logic circuit board for use
6 by the patient. These values are then used by logic board 19 as the pre-determined
7 adjustable threshold values. The values are input by manually adjusting physical
8 potentiometers (as shown in Fig. 4), or by automatically adjusting microprocessor-
9 based set-points representing each of the stimulation control parameters.

10 The stimulation parameters, described above, are used for adjusting
11 angular ON and OFF thresholds, time thresholds and lock-out time. These four
12 parameters are sufficient for most cases, but other parameters could be added
13 including the degree to which the signal is filtered.

14 Optimization of the stimulation parameters is demonstrated in the
15 following example.

16 Walking data for one patient is shown in Figures 6 and 7. The patient
17 was fitted with a tilt sensor and a foot switch. A 10 second period of tilt signal and
18 foot switch samples was selected, representing eight of the patient's 8 step cycles.

19 A template was established using the foot sensor data. Foot sensor data
20 below a 0.38 volts threshold (range of 0.0 to 2.5 volts) was interpreted as the foot
21 being on the ground (signal LOW) and data above 0.38 volts was interpreted as the
22 foot being off of the ground (signal HI). Further, a delay of 0.1 seconds was applied
23 for defining the stimulation template from the HI/LOW data signal. More specifically,
24 as shown in Figure 6 and 7, the template dictates that optimally, the leg stimulation

1 should be initiated 0.1 seconds after foot off (at signal HI or > 0.38 V) and be
2 terminated 0.1 seconds after the foot touches down (at signal LOW or < 0.38 V).

3 Unlike the data presented in Figure 5, the tilt sensor data of this
4 particular patient did not exhibit a suitably timed angular OFF threshold (OFF_TH) and
5 instead, leg stimulation was terminated after the maximum time OFF threshold, set
6 (Tmax) by the timer circuit 26, was exceeded.

7 As seen in Figure 6, of the eight step cycles, the actual stimulation was
8 only applied in seven of the cycles; from about 2 seconds on. Practically, this means
9 that the patient's foot was not stimulated for assisting in the flexing of the foot for
10 clearing the ground during the forward swing phase of the leg. This occurred because
11 the previous cycle of the leg did not cause the tilt sensor to reach the angular OFF
12 threshold (point C) specified by the potentiometer setting for clearly indicating the
13 termination of the patient's step cycle. It was only at about 2 seconds (point D) that
14 the leg angle did finally drop below the OFF threshold and the end of a step cycle was
15 clearly delineated.

16 The original and optimized parameters are presented in Table 2 below:

17 Table 2

	ORIGINAL	OPTIMIZED
18 ON_TH	5 °	10 °
19 OFF_TH	-5 °	-8 °
20 T max	0.53 s	0.62 s
21 T lock	0.14 s	0.14 s
22 Total Error	14 %	5 %

1 As shown in Figure 6, when the patient was tested with the original
2 parameter settings, the stimulator circuit demonstrated a 14 % error when compared
3 to the template. The missed first step contributed greatly to the larger error. After
4 optimization (Figure 7), the error was reduced to 5 % by varying three of the four
5 parameters noticeably, namely, the tilt angle sensor ON and OFF thresholds (ON_TH,
6 OFF_TH) and the maximum stimulation time (Tmax). In particular, it was the raising
7 of the OFF_TH from - 5 ° to - 8 ° which captured the first step cycle and would result
8 in improved stimulation performance in future walking trials.

9 Clearly, while additional trials may be still performed to fine tune the
10 parameters or define a set of parameters for differing physiological conditions,
11 optimization can be achieved without unduly subjecting the patient to the large number
12 of iterations that the optimization process can perform.

1 THE EMBODIMENTS OF THE INVENTION IN WHICH AN
2 EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS
3 FOLLOWS:

4
5 1. A functional electrical stimulator, for use on a human limb,
6 comprising a garment carrying the stimulator components including electrodes
7 for emitting pulses to stimulate the limb, sensor means for monitoring
8 movement of the limb and emitting signals indicative thereof, control circuit
9 means for processing the signals and initiating and terminating stimulation at
10 appropriate times for appropriate periods, and battery means for supplying
11 electrical power to the components, characterized in that:

12 the stimulator (1) is for use on a leg;

13 the garment is a band (2), mountable on the leg;

14 cathode and anode electrodes (9, 10) are carried by the band in a fixed
15 condition;

16 means (7) are carried by the band for reproducibly positioning the band
17 so that the electrodes are located at specified stimulation locations;

18 sensor means (17) are carried by the band in a fixed condition, for
19 measuring the angular position of the leg during movement and emitting
20 sensor signals indicative thereof;

21 control circuit means (19, 20) are carried by the band and are
22 connected with the sensor means and electrodes, for receiving the sensor
23 signals, processing the sensor signals to establish values indicative of the
24 changing angularity of the leg, comparing the established values with
25 predetermined adjustable angular ON and OFF threshold values and initiating
26 and terminating the emission of pulses through the electrodes when the
27 established values reached the ON and OFF threshold values, to stimulate
28 the leg; and

29 the battery means (18) are carried by the band and are connected with
30 the sensor means and control circuit means, for supplying electrical power to
31 them.

AMENDED SHEET

1 2. The stimulator as recited in claim 1 wherein the control circuit
2 means is further operative to establish values indicative of elapsed time,
3 initiated when the leg is stimulated, for terminating the emission of pulses
4 through the electrodes after a pre-determined maximum time, regardless of
5 whether the sensor signal values reach the OFF threshold value.
6

7 3. The stimulator as recited in claim 2 wherein the control circuit
8 means is further operative to establish values indicative of elapsed time,
9 initiated when the leg is no longer stimulated, for preventing premature re-
10 initiation of leg stimulation until the expiry of a pre-determined lock-out period.
11

12 4. The stimulator as recited in claim 1 wherein the control circuit
13 means is operative to process the sensor signals to establish values indicative
14 of the changing angularity of the leg as a function of time and to compare the
15 established values with pre-determined adjustable angular ON and OFF and
16 time threshold values for initiating and terminating the emission of pulses
17 through the electrodes when the established values reach the angular ON and
18 OFF and time threshold values, to stimulate the leg.
19

20 5. The stimulator as recited in claims 1, 2, 3 or 4 wherein the sensor
21 means is a tilt sensor.
22

23 6. The stimulator as set forth in claims 1, 2, 3 or 4 wherein the
24 positioning means are operative to conform to the tibia of the leg and the
25 electrodes are adapted to be located over the common peroneal nerve.
26

27 7. The stimulator as set forth in claims 1, 2, 3 or 4 wherein the
28 positioning means are operative to conform to the tibia of the leg and the
29 electrodes are adapted to be located over the common peroneal nerve and
30 the sensor means is a tilt sensor.
31

1 8. A process for determining new angular ON and OFF and time
2 threshold values for the control circuit means of the functional electrical
3 stimulator defined in claim 4, comprising:

4 storing the sensor signals for the angular position of a user's leg during
5 movement as a function of time;

6 storing template values indicative of the states of stimulation which are
7 required for proper movement of the user's leg, as a function of time;

8 processing the stored angular sensor signals using the control circuit
9 means to establish values indicative of the changing angularity of the limb as
10 a function of time and comparing the established values with predetermined
11 angular and time threshold values so as to determine values indicative of the
12 state of stimulation of the leg as the established values reach the angular ON
13 and OFF and time threshold values;

14 comparing the state of stimulation as determined by the established
15 values and by the template values as a function of time and storing any
16 disparity therebetween as an error value;

17 minimizing the error value by adjusting the angular ON and OFF and
18 time thresholds; and

19 adjusting the angular ON and OFF and time threshold values which are
20 compared by the control circuit means for improved performance at the user's
21 leg.

22
23 9. A process of determining new angular ON and OFF and time
24 thresholds as recited in claim 8 wherein the template values are provided by
25 foot sensor means.

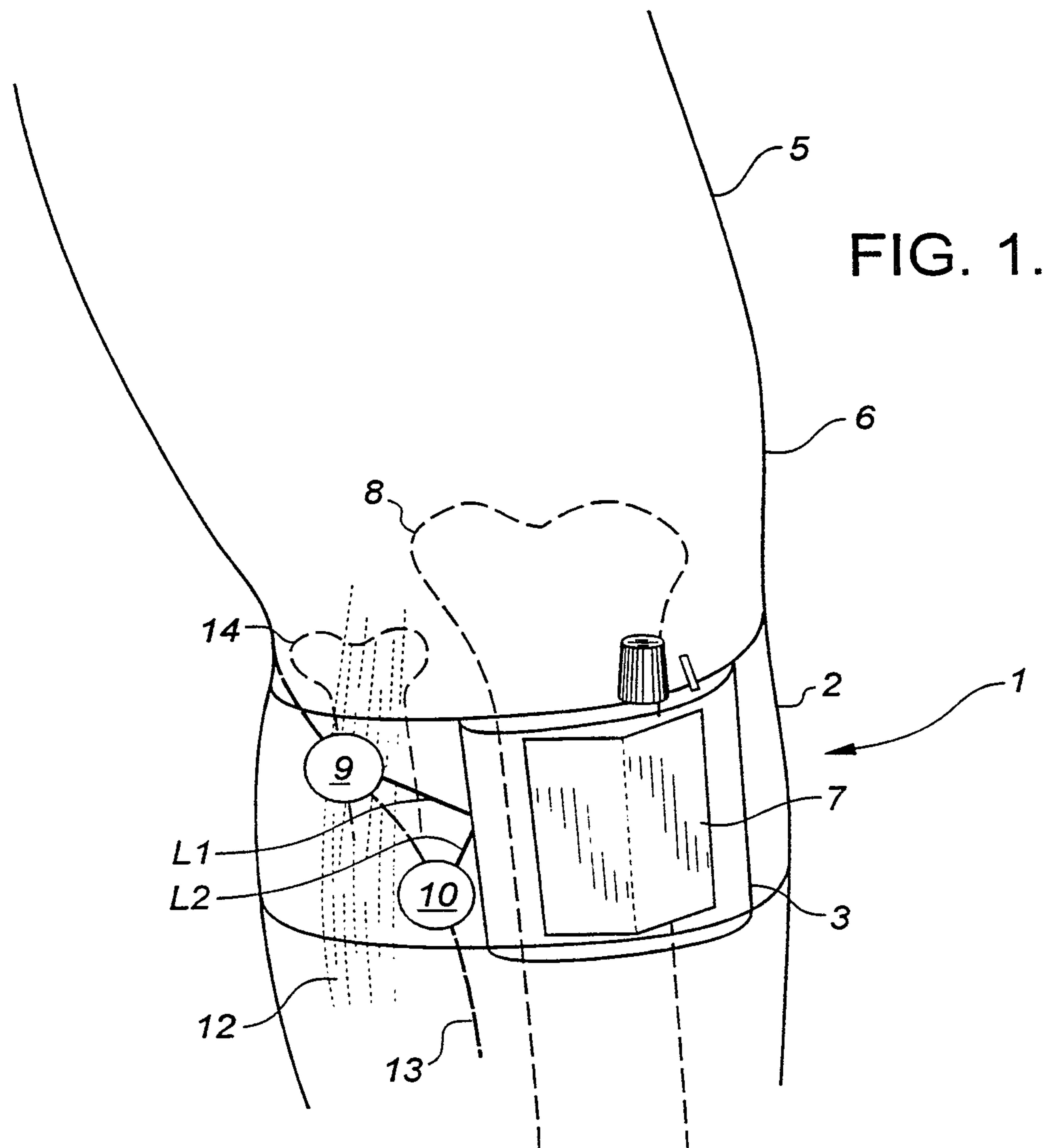
26
27 10. A process for determining new ON and OFF threshold values and
28 elapsed time values for the control circuit means of the functional electrical
29 stimulator defined in claim 4, comprising:

30 providing temporary means for inputting template values indicative of
31 the state of stimulation of the limb, during the leg movement, which is required
32 for proper leg movement;

33 simultaneously sensing the angular position of the leg during the leg
34 movement and emitting angular sensor signals indicative thereof;

1 storing the template values;
2 storing the angular sensor signals;
3 processing the stored angular sensor signals using the control circuit
4 means to establish values indicative of the changing angularity of the leg as a
5 function of time and comparing the established values with predetermined ON
6 and OFF threshold values and elapsed time values and establishing values
7 indicative of the state of stimulation of the leg as the established values reach
8 the angular ON and OFF and time threshold values;
9 comparing the state of stimulation as determined by the established
10 values and the required state of stimulation as determined by the template
11 values as a function of time and storing any disparity therebetween as a first
12 error value;
13 systematically selecting new angular ON and OFF and time threshold
14 values, re-processing the stored sensor signals and re-comparing both the
15 newly determined stage of stimulation and the template stage of stimulation
16 as a function of time and storing any disparity therebetween as a second error
17 value;
18 comparing the first and second error values and selecting the angular
19 ON and OFF and time threshold values which minimize the error signal;
20 repeatably and systematically selecting new ON and OFF threshold
21 values and elapsed time values and comparing the first and second error
22 values until they are minimized; and adjusting the ON and OFF threshold
23 values and elapsed time values used with the control circuit means
24 accordingly for future use.

1/6



2/6

FIG. 2.

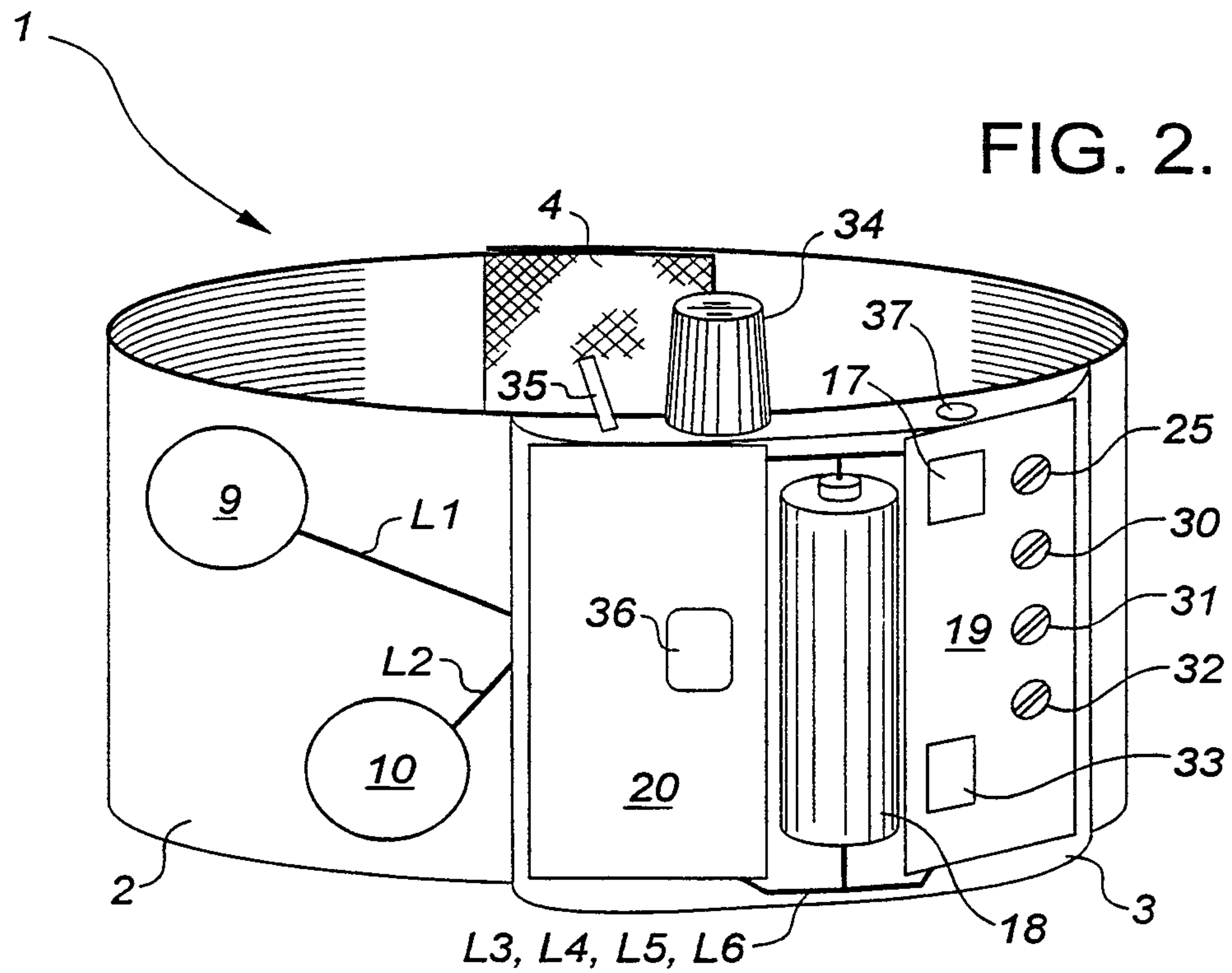
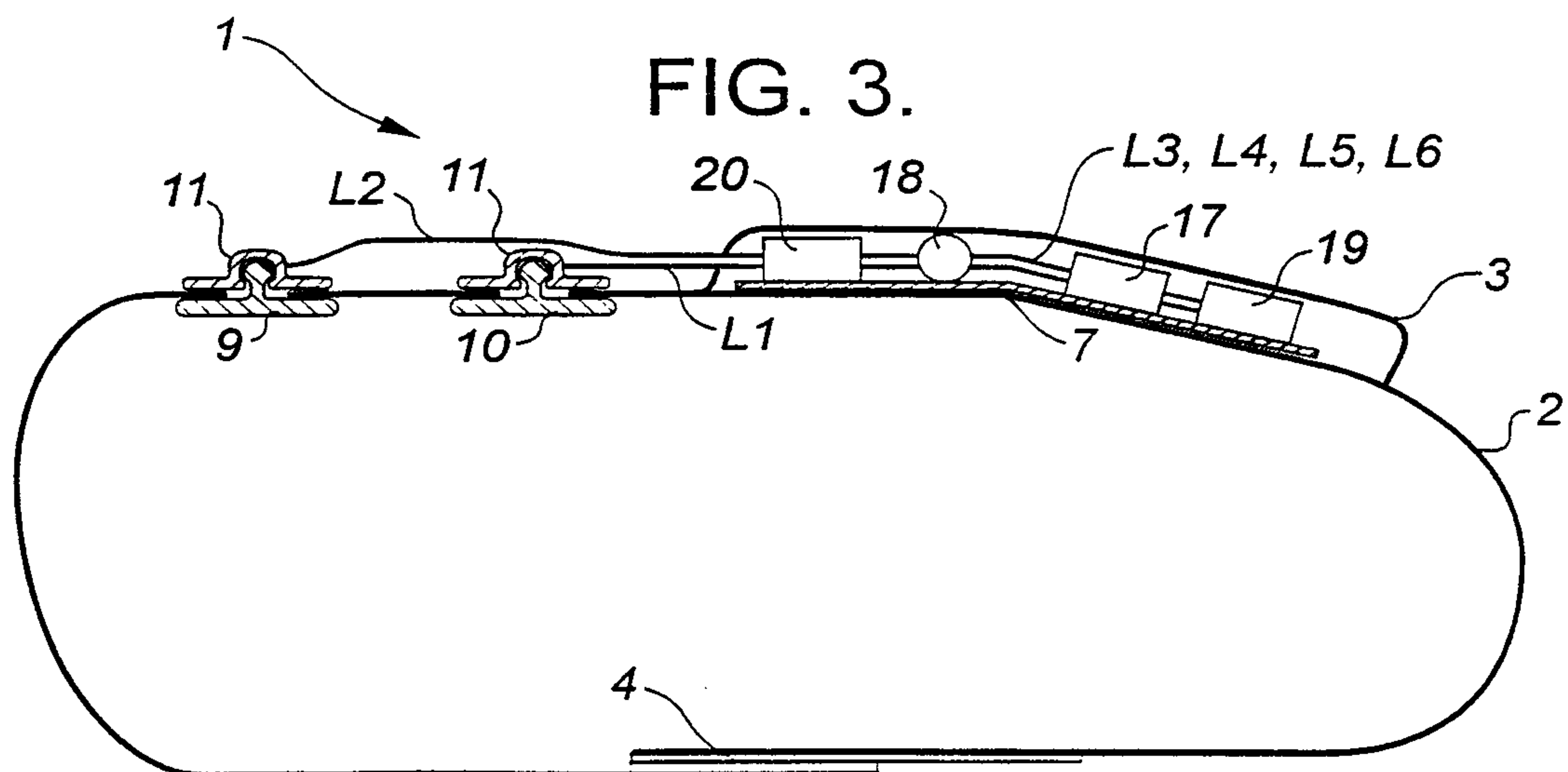
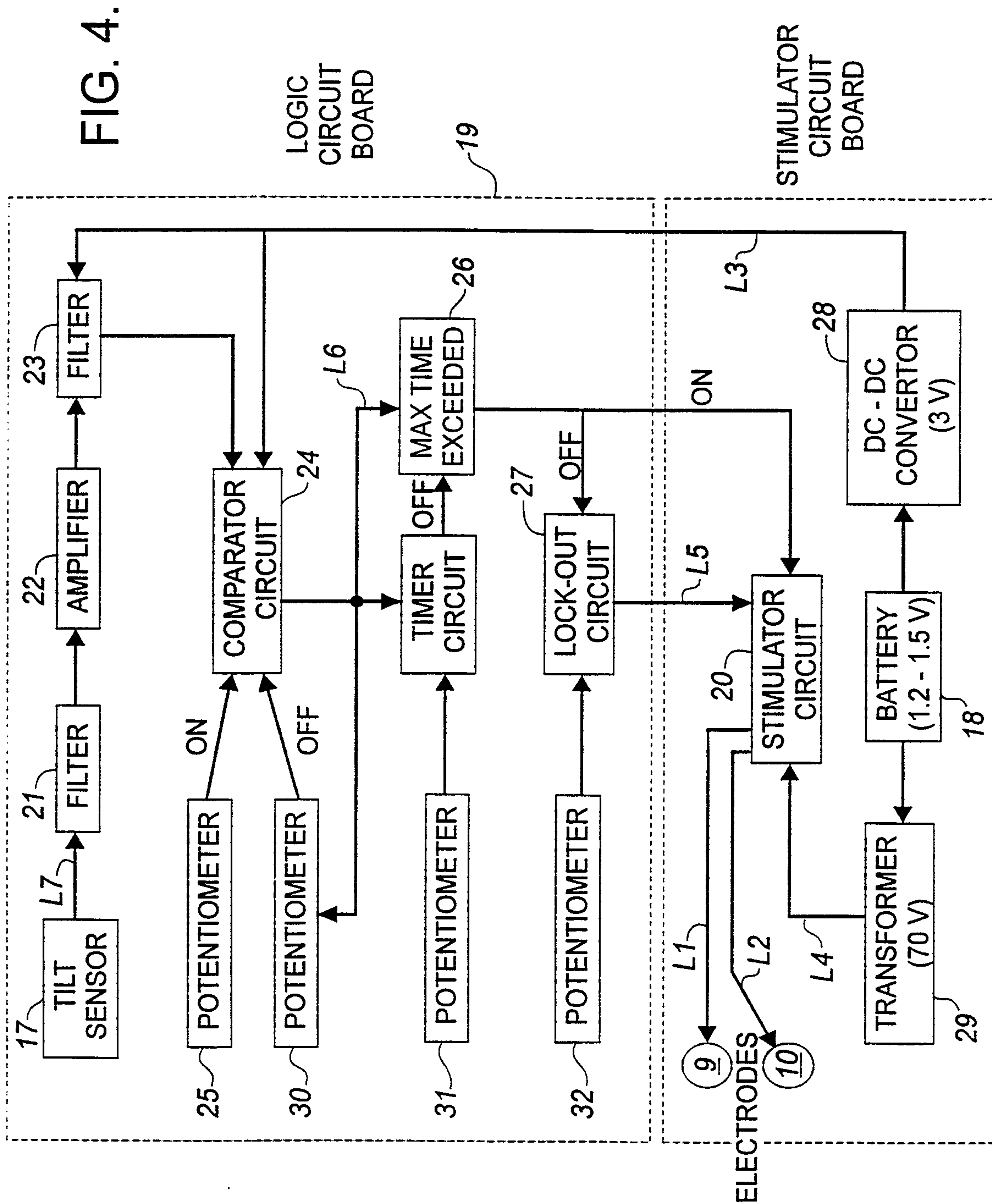


FIG. 3.



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4/6

FIG. 5.

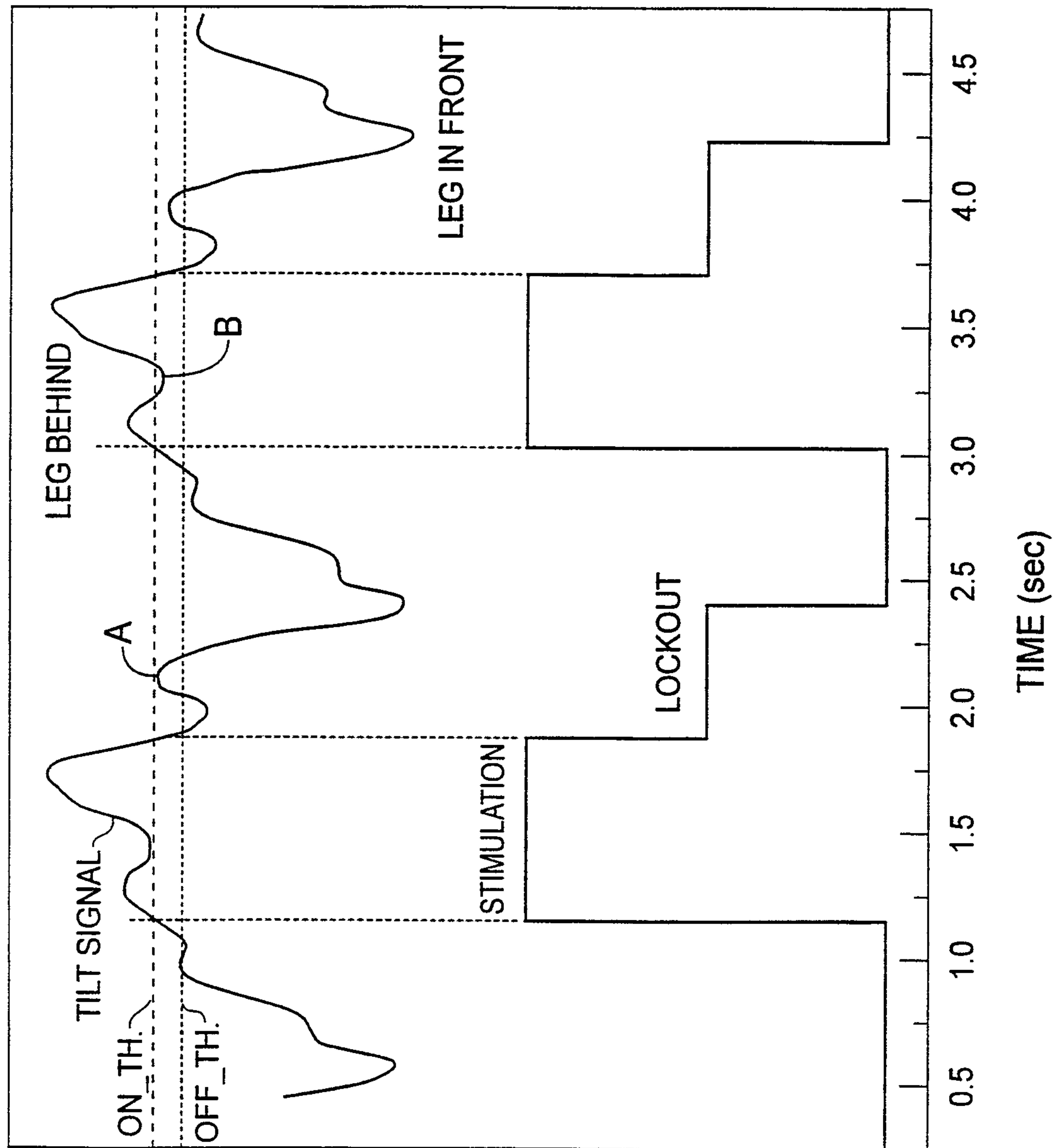


FIG. 6.

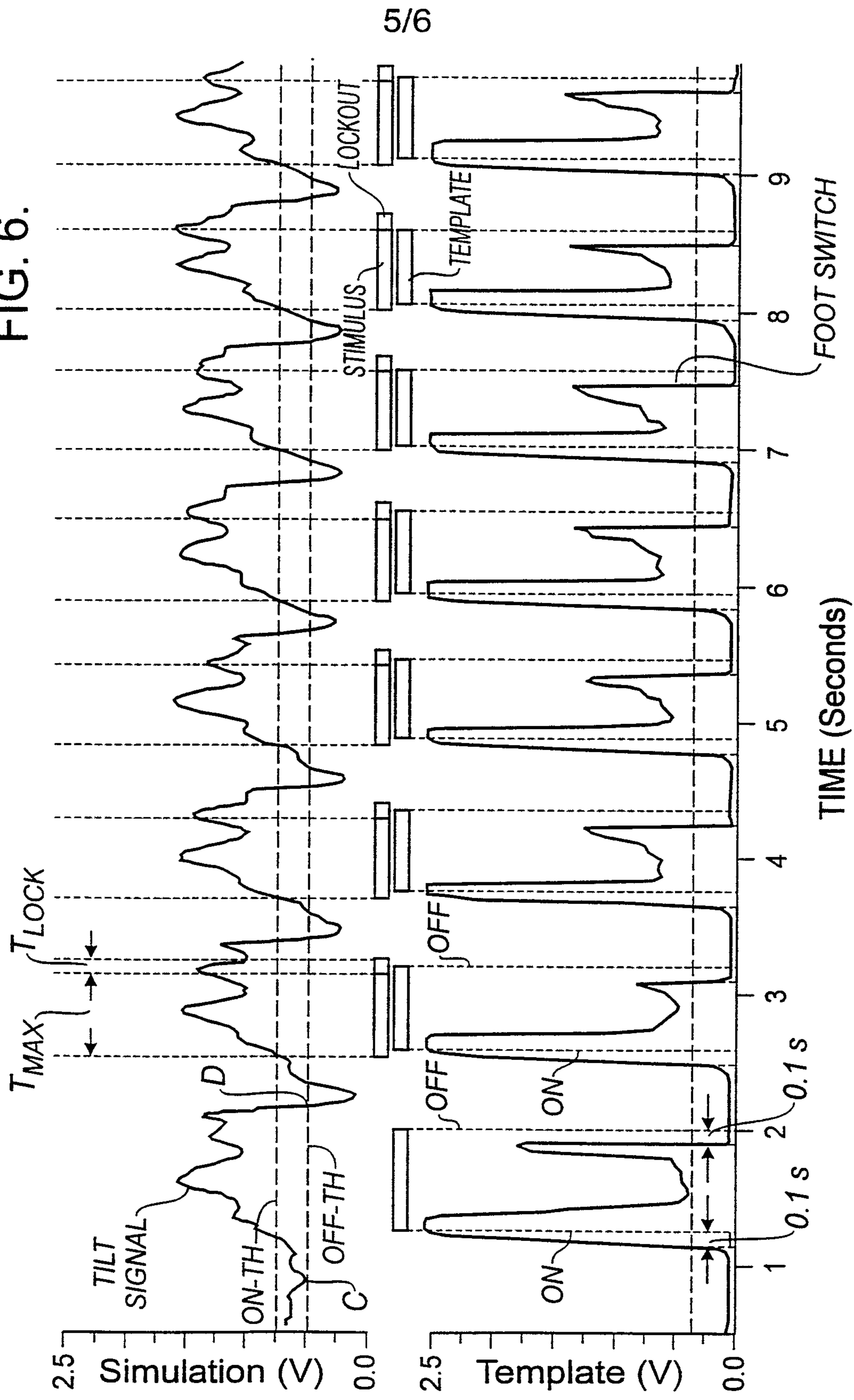


FIG. 7.

