

[54] **METHOD AND STRUCTURE OF PREVENTING AND TREATING ILEUS, AND REDUCING ACUTE PAIN BY ELECTRICAL PULSE STIMULATION**

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[51] Int. Cl.² **A61N 1/36**

[58] Field of Search **128/404, 416-418,**
128/419 R, 421, 422

[56] **References Cited**

UNITED STATES PATENTS

3,411,507	11/1968	Wingrove.....	128/422
3,817,252	6/1974	Maurer	128/416
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[57] **ABSTRACT**

The disclosure is directed to the method and structure of artificially inducing the return of arrested body

functions caused by paralytic ileus and pain associated therewith after surgery or accidental trauma on the human body. The equipment is in the form of electronic circuits producing a generally rectangular or square wave shape which is variable from 10 to 300 pulses per second having a pulse width of 50 to 1,000 microseconds. The circuit includes a pair of constant current amplifiers capable of supplying two different output signals having a pulse amplitude of 80 milliamperes maximum current to provide a current density range of 1 to 50×10^{-6} amperes per square millimeter depending on the electrode area or size. Electrodes are connected to current generators and placed on the body in the area of the lower abdomen in accidental trauma or close to the area of incision post operatively. Posterior electrodes may also be placed on the body as well as over the nerves and particularly the intercostal nerves leading to the site of the incision to further aid in restoring body functions.

Electrodes are also connected to current generators and placed on the body at various locations where a traumatic condition and/or surgery produce a number of localized areas of pain. The application of the electrical pulses stimulates the body and restores its body functions and alleviates the normal problem associated with surgery in the chest cavity, the abdominal cavity and also generally reduces the pain associated therewith.

The use of electrodes may also be connected to current generators and placed adjacent to, or within a localized area in the treatment or prevention of paralytic ileus without regard to what brought it on.

12 Claims, 4 Drawing Figures

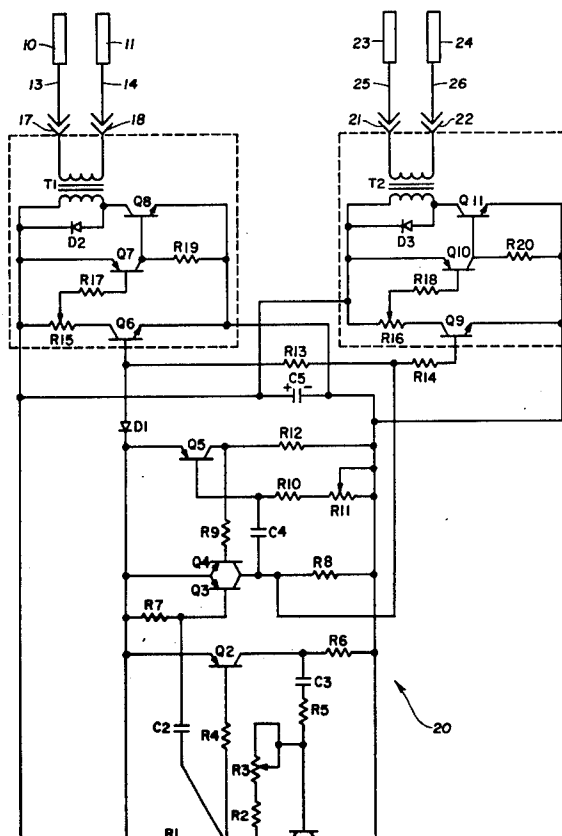


Fig. 1

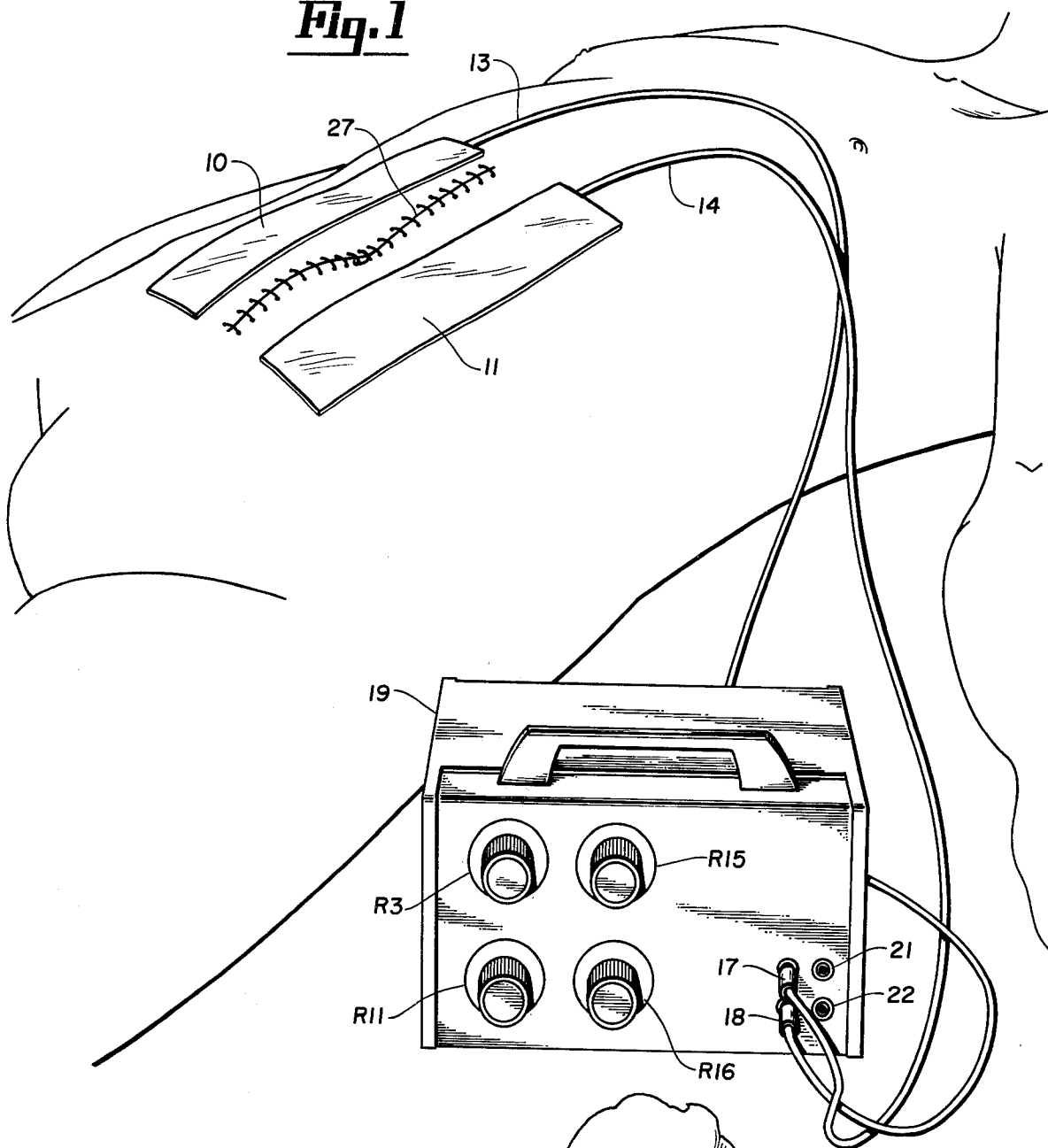


Fig. 2

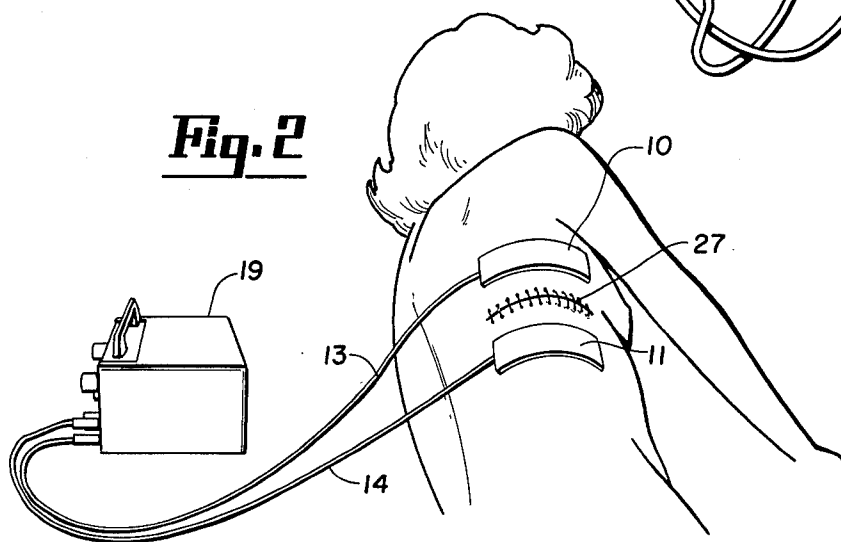


Fig. 3

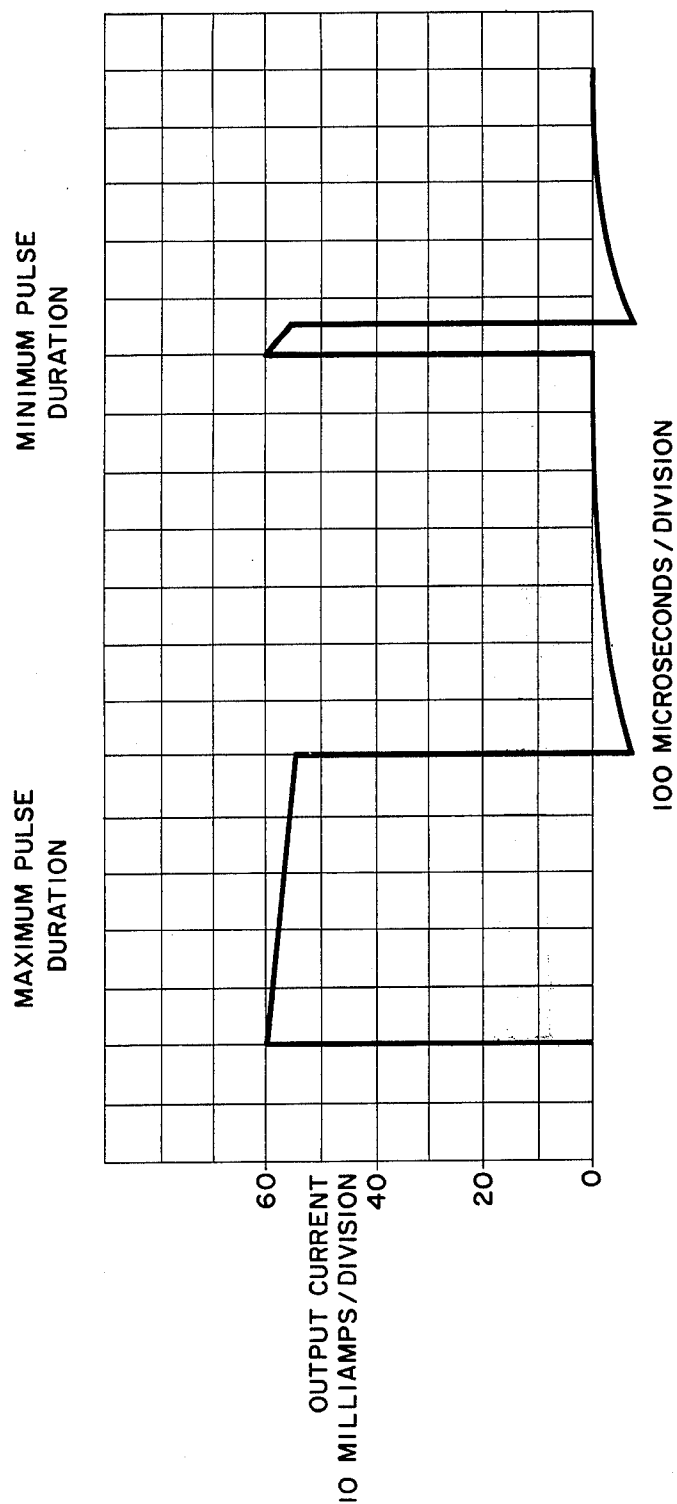
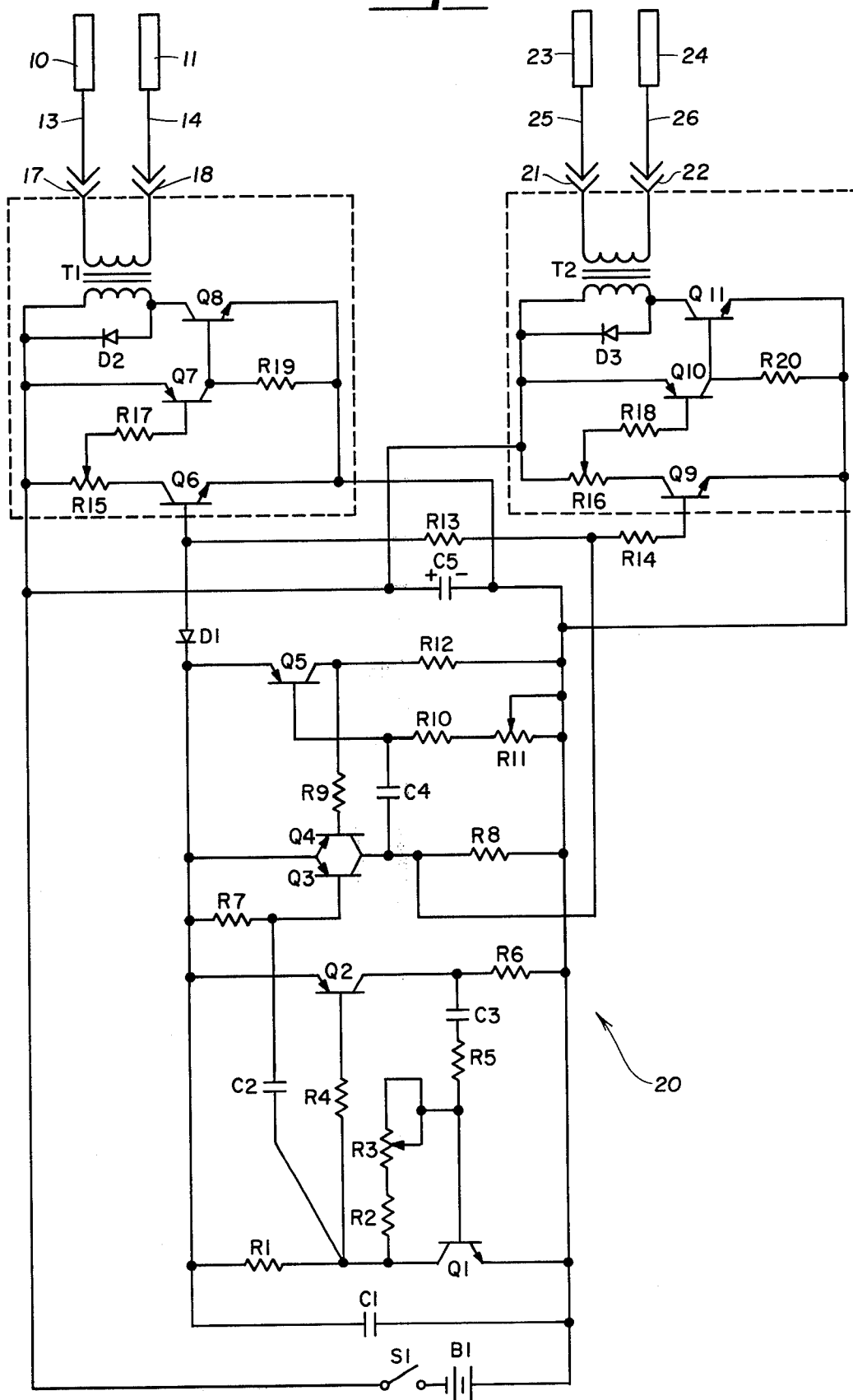


Fig. 4



METHOD AND STRUCTURE OF PREVENTING AND TREATING ILEUS, AND REDUCING ACUTE PAIN BY ELECTRICAL PULSE STIMULATION

This application relates to a method and structure for electrical stimulation of the body to restore arrested body functions and more specifically to treating or preventing paralytic ileus and the pain associated with accidental trauma and surgery.

It is well known that when abdominal surgery is performed, a condition will generally be found characterized by inadequate peristaltic activity (a forward motion of the bowel) affecting the gastro intestinal system completely or locally which may result in paralytic ileus. Prolonged loss of the peristaltic activity of the gastro intestinal track generally leads to distension of bowel loops with fluid and gas. If prolonged, a vicious cycle may occur and the more distension that occurs, the more paralyzed the bowel becomes. Paralytic ileus may also result from conditions other than surgery such as accidental trauma or from a pathological condition.

The management of this condition has been treated by numerous means, directed at relieving distension by means of tube suction in the stomach and intestine. An internal electrical means attached to a suction tube to correct this situation is found in U.S. Pat. No. 3,411,507 but is also generally known that the results achieved by the method set forth therein has also been somewhat inconsistent and incomplete.

It has also been well established that complications of the lung tissue may result from chest operations or accidental trauma and this may take the form of a partial internal collapse of the lung (called atelectasis). A significant reduction of post operative or traumatic pain allows deep respiration and coughing, thus preventing and treating atelectasis.

During the initial phases of the development of the treatment and method of placement of the electrodes in carrying out our invention and discovery, the patients were treated intermittently once or twice a day for a period of 20 to 30 minutes. It has also been established that for treatment of pain the best placement of the electrodes on the patient is close to the surgical wound or site of trauma. Generally, the best results have been achieved by keeping the electrodes substantially parallel to the incision and on some occasions by placing a second pair of electrodes on the body covering the nerves leading to the site of the incision. Where the area of pain is produced by some means other than surgery, generally the electrodes are secured to the body within the localized area of pain. However, good results have also been achieved through the use of posterior electrodes alone and of course where there are multiple areas of trauma such as may result from an accident it may be necessary to use a number of electrodes placed near the traumatic areas and require more than one generator to energize the same.

The electrodes are formed of aluminum foil or other flexible electrically conductive material. They are generally secured to a piece of clear vinyl material or other flexible insulative backing material which will conform to the contour of the body. It has been found that the electrodes having a surface area greater than 3 square inches, depending upon the size of the surgical incision or localized area of pain and up to 30 square inches generally give the maximum flux density penetration of the body that is required to correct the body function

and pain associated therewith. The current density has been found to have a range of approximately 1 to 50 microamperes per square millimeter, and is related to the electrode area or size and the location of the same with respect to the area to be treated.

It was also determined that the use of electrode gel has been superior to the use of wet sponges for connecting the stimulator to the body although generally there were no problems encountered in choice of gel or wet sponge.

In evaluating the method and equipment, various observations were made by comparison to a control group and a group using the structure and practicing the method disclosed herein, and specifically observations were made of: 1. The incidence of post operative complications of ileus and atelectasis. 2. The time spent in the intensive care unit. 3. In thoracotomy patients, the angle their humerus could be raised before and after treatment. 4. The ability of each patient treated to cough.

By way of example, of 250 operations in which the abdominal cavity was opened, where electrical stimulation was used, there were no cases of ileus detected. On the other hand, the expected rate of ileus for the same operation without treatment is generally found to be approximately 13 percent. By way of further example, of 22 patients with protracted ileus secondary to surgery and trauma, treatment with surface electrodes and stimulation as described herein, all patients subsequently developed active bowel tones and within 48 hours the majority had bowel movements signifying a cure. In addition, there was also a significant reduction in the time spent in the intensive care unit for those patients being treated with the electrical stimulation. On an average the length of stay in the intensive care unit was reduced by approximately 1 day.

Thoracotomy patients treated with the electrical stimulation pulses and as contrasted to a similar group of patients who were not treated, showed that five patients of the treated group developed clinical atelectasis confirmed by X-ray for a rate of 13 percent compared to 15 patients of a control group of 30 who had post operative atelectasis in the untreated group for a rate of 50 percent. The treated group had an average stay in the intensive care unit of 3 days compared to 4.2 days for the control group. As a measurement of patient activity following thoracic surgery, patients could raise their arm so that the mean angle of the humerus to the thoracic cage prior to treatment was 91°. Following a few minutes of treatment, the average angle of the humerus to the thoracic cage was noted to be 154°, or an increase of 63°.

By way of further example, where 10 patients were treated as disclosed herein after suffering fractured ribs, only one developed atelectasis, for a rate of 10 percent. Another patient suffering from atelectasis fully recovered after stimulation was applied. Out of 12 patients suffering fractured ribs who were not treated with stimulation as set forth herein, eight developed atelectasis, or in other words, 66 percent developed atelectasis as compared to the 10 percent just described.

Subjective evaluation of these patients, however, revealed a pain reduction of about 80 percent, and as a result, coughing improved as noted by independent observers before and after treatment. The presently described treatment is unlike acupuncture which controls pains by needle stimulation at a distal site.

It became apparent that hyper activity of the gastro intestinal track was reduced by the electrical stimulation and that the majority of the patients treated with this electrical stimulus expelled flatus with a short time thereafter and had a bowel movement soon thereafter. Clinically, the bowel tones became hyper active whereas preceding the stimulation they were hypo active to absent.

It is therefore a general object of this invention to provide a method and structure to induce the return of impaired body functions causing atelectasis and paralytic ileus due to surgery, accidental trauma or pathologic processes.

It is another object of the present invention to provide a method and structure for treating pain in the human body as a result of experiencing a traumatic condition such as surgery or accidental trauma.

It is still a further object of this invention to provide a method and structure for treating pain associated with accidental trauma such as fractured ribs, a fractured clavical, a fractured coccyx, subperiosteal hematomas and all soft tissue injuries and fractured of bones.

It is still another object of the present invention to provide signal generating means for generating signals of predetermined pulse frequency and pulse width for controlling post operative problems of atelectasis and paralytic ileus.

These and other objects and advantages of the invention will more fully appear from the following description, made in connection with the accompanying drawings, wherein like reference characters refer to the same or similar parts throughout the several views, and in which:

FIG. 1 is a diagrammatic view of a patient showing placement of electrodes after abdominal cavity surgery;

FIG. 2 is a diagrammatic view of a patient showing placement of electrodes after chest cavity surgery;

FIG. 3 is a diagram of a typical current pulse wave shape applied to the electrodes; and

FIG. 4 is a schematic diagram of the electrical equipment and electrodes which are attached to the body of the patient.

FIG. 1 discloses a pair of electrodes 10 and 11 which are placed adjacent and parallel to the abdominal incision 12. A pair of conductors 13 and 14 are connected respectively to electrodes 10 and 11 and are also connected to a pair of jacks 17 and 18 at the front of a housing 19 which houses an electrical circuit 20 that will be described in more detail subsequently, and is shown in FIG. 4. Another pair of jacks 21 and 22 are used to energize another pair of electrodes 23 and 24 (FIG. 4) through another pair of electrical conductors 25 and 26 respectively.

FIG. 2 discloses a patient having an incision in the chest cavity and electrodes 10 and 11 are shown placed substantially parallel to and running the length of the incision. It was found that during the various applications of the electrodes and use of the equipment that the optimum results were obtained by using a pulse width of approximately 200 to 400 microseconds with a frequency of 100 to 160 pulses per second.

FIG. 4 shows the electrical circuit 20, which generates the electrical signals. Transistors Q1 and Q2 are connected in the form of a free running multivibrator producing a rectangular or square pulse wave, the frequency of which is controlled through a setting of vari-

able resistor R3 and capacitor C3 to adjust the frequency or repetition rate. The repetition rate is adjustable from approximately 10 to 300 pulses per second.

A pulse width circuit is formed from transistors Q3, Q4 and Q5 which are connected to the multivibrator or oscillator through a capacitor C2. The pulse width is determined by a time constant developed through an RC network of capacitor C4 and variable resistor R11, and is adjustable from 50 to 1,000 microseconds. A pulse signal is obtained from the junction of the collectors of transistors Q3 and Q4. The signal is applied to the bases of transistors Q6 and Q9 through resistors R13 and R14. The signals are amplified and appear across variable resistors R15 and R16 connected respectively to the collectors of transistors Q6 and Q9. The first output stage further amplifies the signal through transistors Q7 and Q8 to provide a constant current output which is independent of the load through transformer T1. Diode D2 is used to reduce the inductive voltage due to the collapse of the field at transformer T1.

The second output circuit also includes a pair of transistors Q10 and Q11 which further amplify the signal received from Q9 and apply the same to an output transformer T2 which also provides a constant current output signal independent of the load connected thereto. Diode D3 acts in a manner similar to that of diode D2 in controlling the induced current flow through transformer T2. Variable resistors R15 and R16 provide a means of varying the amplitude at the two output stages which may have a peak current amplitude, adjustable from 10 to 80 milliamperes. Expressed in a different manner, the electrical pulses generated should produce a peak current density range of approximately 1 to 50 microamperes per square millimeter of electrode area depending on the electrode size and its placement on the body with respect to the area to be treated or controlled. While the wave shape shown in FIG. 3 has proven to be an optimum shape, it should also be understood that other peaked wave forms may be used such as triangular or saw tooth waves and those having some slope to their leading or trailing edges.

A diode D1 is connected in series with the supply battery B1 and the connection to transistors Q1, Q2, Q3, Q4, and Q5 forming the pulse generator to decouple the generator and output stages. Upon closing switch S1, power is applied to the pulse generator and pulse width circuits as well as the current amplifiers, to supply an output voltage of the characteristics disclosed in FIG. 3.

Through the use of the teaching as disclosed herein, it will be apparent that post operative pain, traumatic pain and other post operative complications may be alleviated so that the patient may resume deep breathing and coughing thus reducing pulmonary complications for surgery performed in the chest and abdominal cavities. Through the use of electrical stimulation as disclosed herein, paralysis of the bowel is alleviated, thus preventing post operative ileus, a condition of paralysis of the bowel leading to distension with fluid and gas which may lead to complication of bowel obstruction. As a result of the beneficial treatment described herein, there is a marked reduction of pulmonary complication and bowel paralysis resulting in a reduced hospital stay by the patient in an intensive care unit. Electrical stimulation, upon being applied to the localized area of pain

and particularly adjacent each side of an incision, or area of pain, is generally given to the patient on a continuous basis for two or three days, or stimulation may be used intermittently from 20 to 30 minutes every 2-4 hours.

It has been found that reduction of pain permits the return of certain body functions such as deep breathing and coughing which may have been reduced due to accidental chest trauma resulting from fractured ribs and/or pulmonary contusions, i.e., hemorrhaging within the lungs. Similar results may be achieved in preventing ileus following trauma from a fractured pelvis and/or hematoma in the retro peritoneal space, i.e., the area posterior to the abdominal cavity. In other words, stimulations by the electrical signals through the method and equipment disclosed herein has proven to be extremely helpful in the control of post traumatic pain due to fractured ribs, a fractured clavical, and subperiosteal hematoma of the leg and other sites of fractures of bones or soft tissue contusions.

It has also been found that the use of posterior electrodes may function well by themselves without regard to their use with electrodes in a localized area. Where multiple applications are needed it may be necessary to use two units such as disclosed herein, particularly where multiple areas of application are required.

Through the teachings disclosed herein, treatment or control of pain in the chest cavity or abdominal cavity caused traumatically, that is by accident, or by surgery, has proven to be highly successful.

It will, of course, be understood that various changes may be made in the form, details, arrangement and proportions of the parts without departing from the scope of the invention which consists of the matter shown and described herein and set forth in the appended claims.

What is claimed is:

1. The method of treating pain in the human body as a result of experiencing a traumatic condition such as surgery or accidental trauma including the steps of:

- a. generating a series of electrical rectangular, single frequency, fixed duration pulses within the range of 50-1000 microseconds duration and the repetition frequency range of approximately 10-300 pulses per second and of substantially constant amplitude;
- b. securing at least a pair of rectangular body electrodes in juxtaposition on the skin surface and parallel to the localized area of traumatic pain in the body;
- c. and applying said series of electrical pulses to said body via said electrodes with a current density of 1-50 microamperes per square millimeter continuously for a period of 20-30 minutes every 2-4 hours until the pain caused by said traumatic condition is observed to be substantially overcome.

2. The method as set forth in claim 1 wherein the step of securing at least a pair of body electrodes includes providing each electrode-body interface for electrical current flow of 3-30 square inches.

3. The method as set forth in claim 2 including the steps of:

- securing at least a second pair of body electrodes posteriorly to the localized area of pain in the body whereby said electrodes cover the nerves leading to the site of the pain; and
- applying said series of electrical pulses to said posteriorly positioned pair of body electrodes similarly as with said locally positioned pair of electrodes.

4. The method as set forth in claim 3 wherein the step of generating a series of electrical pulses includes generating said pulses with a peak current amplitude of 10-80 milliamperes.

5. The method of treating pain in the human body as a result of experiencing a traumatic condition such as surgery or accidental trauma including the steps of:

- a. generating a series of electrical rectangular pulses of 200-400 microseconds duration having a repetition frequency of approximately 100-160 pulses per second and of substantially constant amplitude;
- b. securing at least a pair of rectangular body electrodes posteriorly to the localized area of traumatic pain in the body whereby said electrodes cover the nerves leading to the site of the pain;
- c. and applying said series of electrical pulses to said body via said electrodes with a current density of 1-50 microamperes per square millimeter continuously until the pain caused by said traumatic condition is observed to be substantially overcome.

6. The method as set forth in claim 5 wherein the step of generating a series of electrical pulses includes generating said pulses with a peak current amplitude of 10-80 milliamperes.

7. The method of treating or preventing paralytic ileus in the human body brought on after surgery, accidental trauma or pathological conditions including the steps of:

- a. generating a series of rectangular electrical pulses of 50-1,000 microseconds duration having a repetition frequency of approximately 10-300 pulses per second and of substantially constant amplitude;
- b. securing at least a pair of elongated body electrodes on the skin surface of the body in juxtaposition to at least one of a surgical incision made in the body, a localized area of accidental trauma, or a localized area formed by a pathological condition;
- c. and applying said series of electrical pulses to said body via said electrodes with a current density of 1-50 microamperes per square millimeter continuously until the paralytic ileus is observed to be substantially overcome, or prevented.

8. The method as set forth in claim 7 including the steps of:

- securing a pair of body electrodes posteriorly to cover the nerves leading to any surgical incision made in the body, any localized area of accidental trauma, or any localized area formed by a pathological condition; and
- applying said same series of electrical pulses at said same current density to said posteriorly positioned electrodes as to said juxtapositioned electrodes.

9. The method as set forth in claim 8 where the step of securing at least a pair of elongated body electrodes includes providing each electrode with a contact surface of 3-30 square inches.

10. The method as set forth in claim 9 wherein the step of generating a series of electrical pulses includes generating said pulses with a peak current amplitude of 10 to 80 milliamperes.

11. Apparatus for treating pain and for treating and preventing paralytic ileus in the human body resulting from a traumatic condition, such as surgery or accidental trauma, said apparatus comprising:

- a. a pulse generator generating a substantially rectangular wave signal having a repetition rate of

- 10-300 pulses per second and a pulse width variable from 50 to 1000 microseconds duration;
- b. a pair of current generating means being excited by said pulse generator and each having an output circuit independent of a load to be connected thereto, said means each being individually adjustable to supply a pulse amplitude of 10 to 80 milliamperes;
- c. a plurality of flexible elongated electrodes being positionable to the skin surface of the human body substantially within the localized area of pain, said electrodes each having a current conduction area

- of 3-30 square inches;
- d. and a plurality of electrical conductors connecting said plurality of electrodes to said pair of current generating means.

12. The structure as set forth in claim 11 including:

e. an electrical current conducting gel applied to said body electrodes and contacting the human body, being in cooperation with said electrode in the conduction of current wherein the current density is 1-50 microamperes per square millimeter.

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