

- [54] **METHOD AND APPARATUS, INCLUDING A FLEXIBLE ELECTRODE, FOR THE ELECTRIC NEUROSTIMULATION OF THE NEUROGENIC BLADDER**
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- [52] U.S. Cl. **128/419 E**, 128/418
- [51] Int. Cl. **A61n 1/36**
- [58] Field of Search 128/418, 419, 421, 422

[56] **References Cited**

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3,421,511 1/1969 Schwartz et al. 128/418

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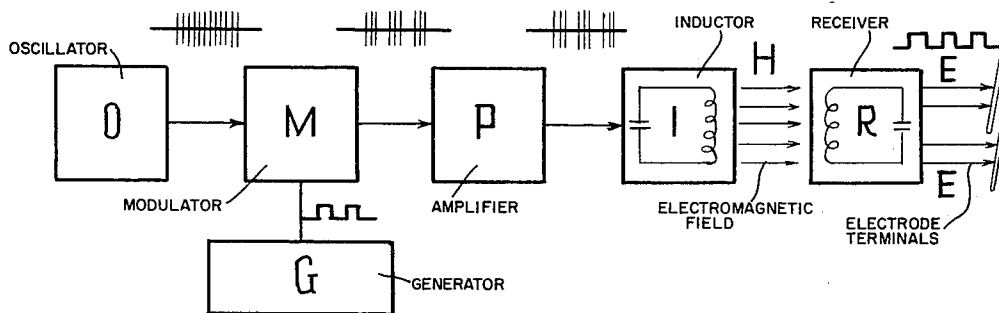
Burghela et al., *Rumanian Medical Review*, Vol. 3, No. 1 1959, pp. 48-51

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[57] **ABSTRACT**

A method for artificial voiding of the bladder involves the introduction of electrodes onto the motor nerves of the bladder, and placing on the anterior wall of the sacrum a receiver means for producing an electric current within such electrodes when excited by an electromagnetic field, and periodically applying an electric and an electromagnetic field from the exterior of the body to said receiver means to induce voiding of the bladder.

10 Claims, 5 Drawing Figures



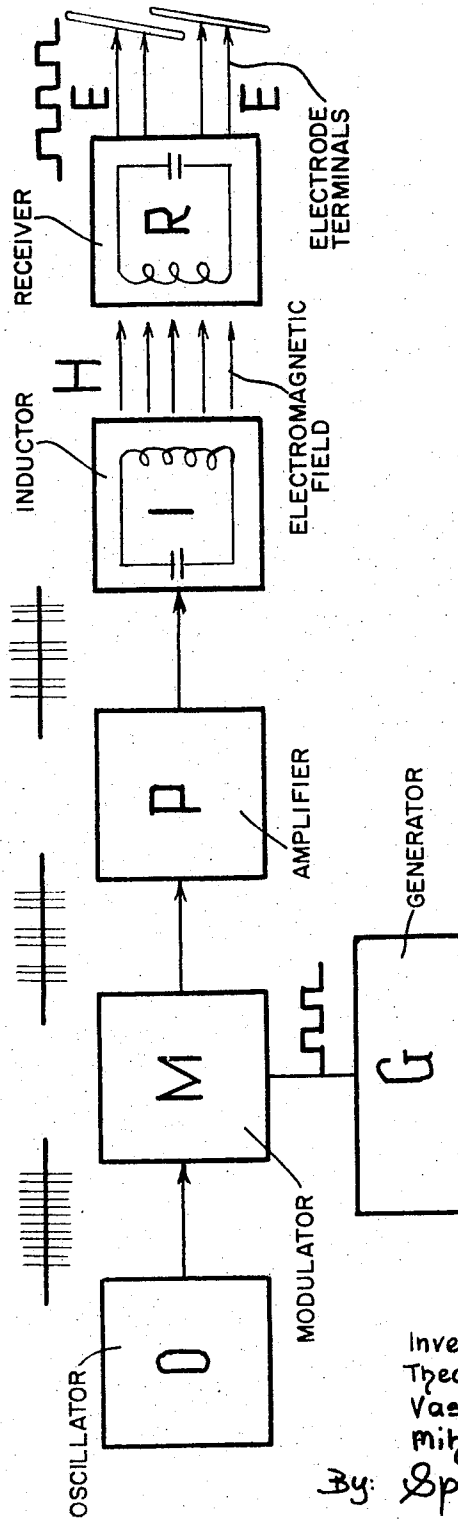


Fig. 1

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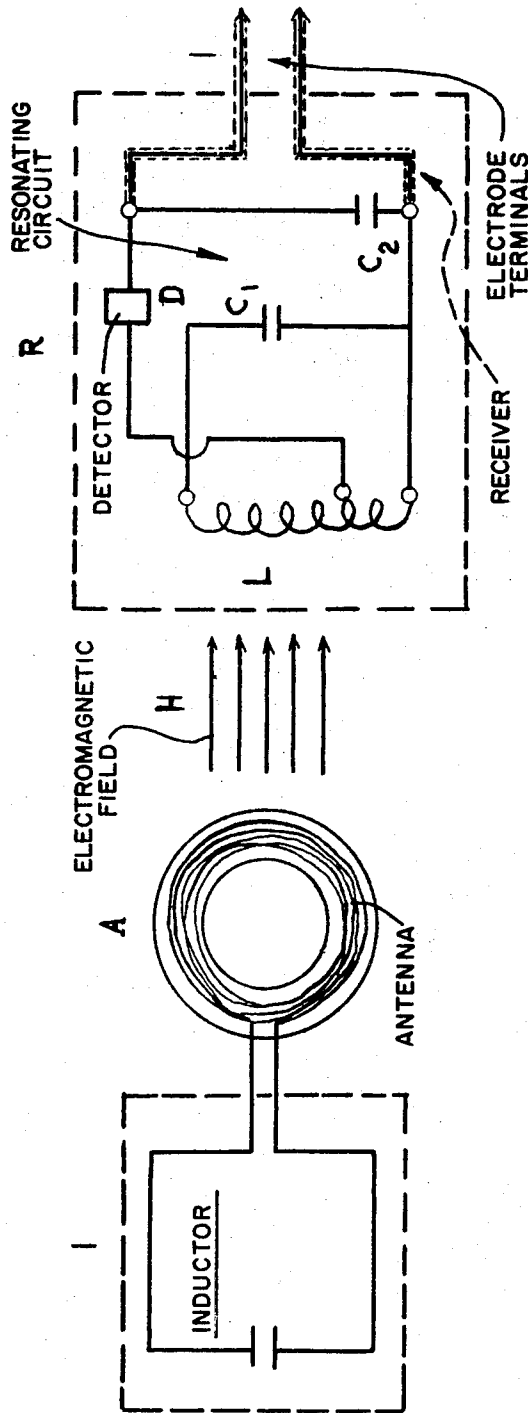


Fig. 2

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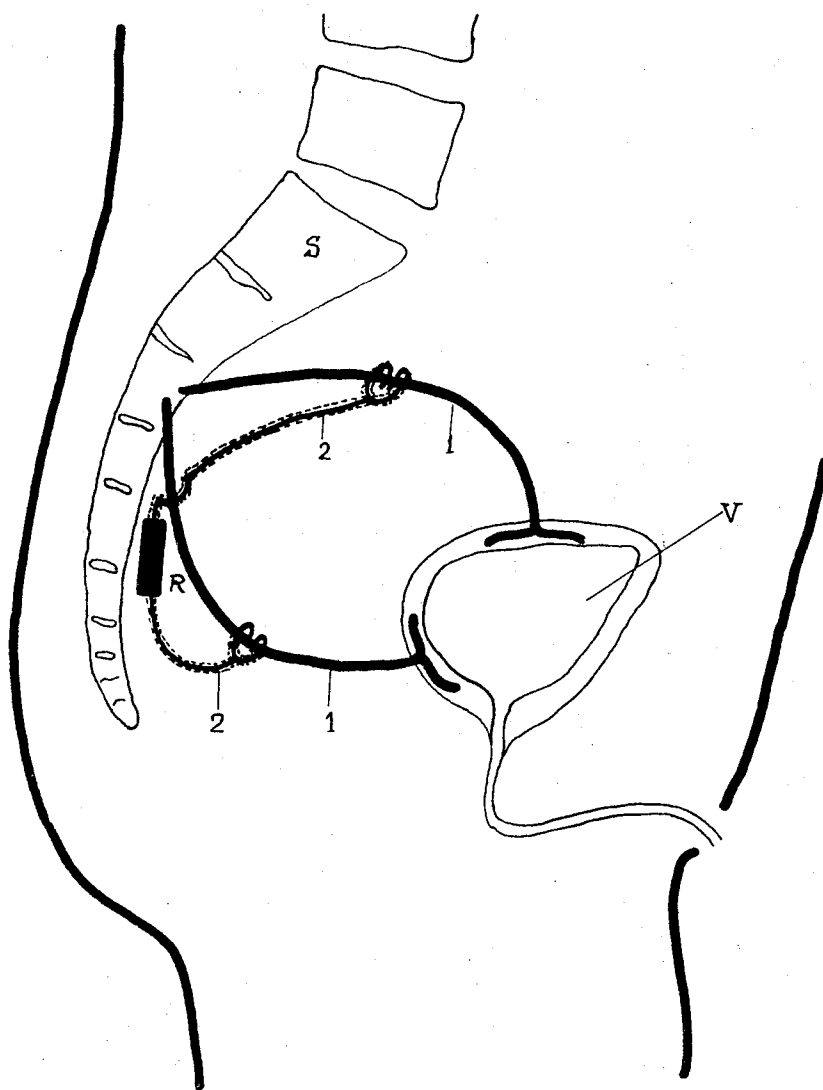


Fig. 3.

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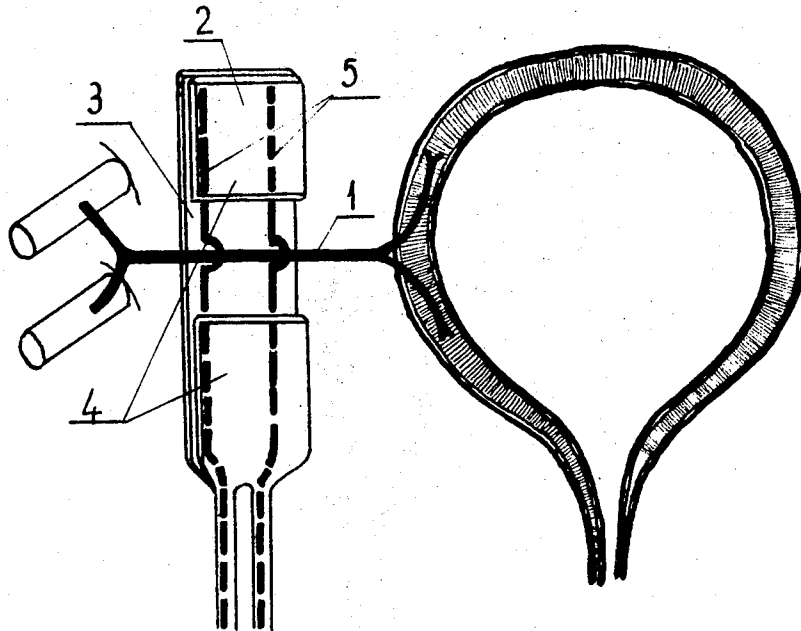


Fig. 4

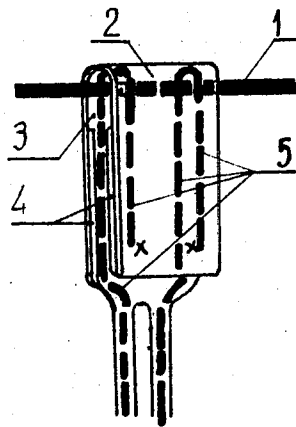


FIG. 5.

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METHOD AND APPARATUS, INCLUDING A FLEXIBLE ELECTRODE, FOR THE ELECTRIC NEUROSTIMULATION OF THE NEUROGENIC BLADDER

The invention relates to a method and an apparatus for the electric neurostimulation from a distance of the neurogenic bladder following spinal cord injuries as well as other affections of the nervous system.

Several methods of treatment of urine retention as a consequence of spinal cord injuries and of other affections of the nervous system are known:

a. The intermittent catheter drainage which, on one side presents the disadvantage of urinary tract infection with all its complications (calculosis, pyelonephritis, uremia) and on the other side the impossibility of being applied in all cases (urethral strictures, rupture of the urethra, and so on).

b. The permanent catheter drainage, which represents a yet greater danger of infection, compromising of the muscular and elastic tissue of the bladder, uremia, etc.

c. Cystostomy, nearly abandoned, which besides the danger of infection delays the recovering of the bladder reflex and causes a great inconvenience for the patient.

d. Another direct electric stimulation of the bladder muscle is known, which consists in its stimulation with electrodes of stainless steel wires or disks fixed on the bladder wall, electrodes which are bound to a receiver surgically applied under the skin, and started by an external transmitter with small power of penetrability.

On account of the high electromotor tension induced, up to 40 volts, this method presents the disadvantage of producing pain during the stimulation, contractions of the lower extremities and abdomen muscles, burns and scars at the stimulation site as well as perforations of the bladder wall, the interruption of the conductors by motion, all drawbacks that counterindicate or limit the possibility of applying this method.

The method, according to the invention, eliminates the above mentioned disadvantages in that, in order to avoid the catheter drainage, infections, complications and the drawbacks resulting from the application of electric stimuli, on the bladder muscle, the electric stimulation of the bladder motor nerves in man is applied, by using a receiver surgically introduced onto the anterior wall of the sacrum, provided with two bipolar electrodes, one for each pelvic nerve, the electrodes being fixed on these nerves, which receive from the receiver rectangular stimuli having variable parameters, comprised between 5 and 10 ma., an electromotor tension of about 2.5 volts, a frequency of 15 - 20 impulses and a stimulus duration up to 7 ms., the stimulus being introduced into the receiver by an electromagnetic field, produced by the antenna of an external transmitter.

The apparatus according to the above method consists of an external inductor, the antenna of which produces an electromagnetic field with great power of penetrability into the body and which exerts an influence on a receiver previously placed onto the anterior wall of the sacrum, composed of an oscillating circuit accorded with the frequency of the external inductor, the secondary circuit of which in feeding a detector (a germanium diode) the current being filtered by means of a capacitor and applied at the electrode terminals, electrodes which are wrapped around the nerves.

The application of the invention is illustrated in the following example in relation to FIGS. 1, 2, 3, 4 and 5, which represent:

FIG. 1 is a schematic block diagram of apparatus according to the present invention.

FIG. 2 is a schematic diagram showing in greater detail the inductor and receiver of FIG. 1.

FIG. 3 is a detail of the position of the receiver and electrodes in the body.

FIG. 4 is a schematic detail of the electrodes and of their position on the pelvic nerves.

FIG. 5 is a detail of folding of the electrode on the pelvic nerves.

According to the invention, the apparatus emitting electromagnetic waves, is composed of a generator G (FIG. 1), which produces rectangular impulses with the following characteristic: 5 - 10 ma., 15 impulses per second, and a duration of 7 ms.

The generator G, by means of a modulator M, modulates an electric current with a frequency of 300 kHz., oscillations supplied by an oscillator O. Having been amplified by the amplifier P, the electric current reaches an inductor I, the resonant circuit of which produces by means of an exterior antenna A (FIG. 2), an electromagnetic field H with great power of penetrability into the body.

The electromagnetic field H exerts an influence on a receiver R, previously fixed on the anterior wall of the sacrum, composed of a resonant circuit LC₁ (FIG. 2), accorded with the frequency of the exterior inductor, the secondary circuit of which feeds a detector D (germanium diode), the current being then filtered by means of a capacitor C₂ and applied at the electrode terminals E.

The application of the method consists in:

dissection of the pelvic nerves (1) (FIGS. 4 and 5), on which are applied the bipolar electrodes (2), composed of two foils (3) and (4) (FIGS. 4 and 5), made of plastics, for instance polyethylene, the external foil (3) being continuous and the interior one (4) being interrupted in the central zone for an adequate distance, two platinum wires (5) being introduced between the foils, so that by folding (FIG. 5) an intimate contact with the pelvic nerves surface (1) is obtained, in this way the electrode being sewed in two points.

The receiver R (FIG. 3) is located on the anterior wall of the sacrum S, retroperitoneally, the pelvic nerves (1) receiving electric stimuli from the electrodes (2) during all the period of time in which the antenna is situated parallel to the receiver and in the area where the receiver is included.

These stimuli, transmitted to the pelvic nerves (1), produce the contraction and voiding of the bladder V (FIG. 3).

Some clinical cases are reported further, in which the electric neurostimulation of the pelvic nerves, according to the invention, was applied in cases of spinal cord injuries.

Case 1. Patient with accidental fracture of the spine at the level of the Xth and XIth thoracic vertebrae. Because of paraplegia with urine retention, drainage with catheter indwelling is carried on. After 3 weeks from the accident, the receiver for the neurostimulation of the bladder is surgically applied, the catheter being taken off.

The artificial voiding of the bladder by neurostimulation is performed; the bladder voids without residue and the urine is sterile on culture.

Case 2. Spinal cord injury with fracture at the level of VIIIth thoracic vertebra. Catheter drainage of the bladder is first and subsequent urinary infection results. After 4 weeks, at the withdrawing of the catheter, the urine retention persists.

The artificial voiding of the bladder by electric neurostimulation is performed. The urine becomes clear and sterile. After 2 months, good results are obtained by voiding with neurostimulation.

Case 3. Urinary infection is present due to permanent catheter drainage in a patient with spinal cord injury and spinal cord section at the level of the VIth thoracic vertebra.

Receiver and neurostimulation, with complete bladder voiding are applied, the clearing and sterilization of the urine being obtained.

The contraction of the paralyzed bladder as a result of spinal cord injuries or other affections of the nervous system is performed, according to the invention, by electric stimulation with a receiver, insulated with polyethylene, surgically introduced into the body and connected with bipolar electrodes which are placed on the pelvic nerves of the bladder.

The receiver is put in action, sending electric stimuli to the pelvic nerves, at the moment when the antenna of an external transmitting apparatus is brought nearer to the zone where the receiver is included.

The voiding of the bladder by electric stimulation of its motor nerves allows the avoiding of the catheter drainage which presents the danger of urinary tract infection with all its subsequent complications.

It will be understood that the above description of the present invention is susceptible to various modifications, changes and adaptations, and the same are intended to be comprehended within the meaning and range of equivalents of the appended claims.

We claim:

- 1. A method for artificial voiding of the bladder comprising (a) surgically introducing electrodes onto the motor nerves for the bladder, (b) surgically placing on the anterior wall of the sacrum receiver means for the producing of an electric current in the electrodes when excited by an electromagnetic field and attaching said receiver means to the electrode to apply the current thereto, (c) generating an electromagnetic field, and (d) periodically applying the electromagnetic field to the receiver means to excite the same and induce voiding of the bladder.
- 2. The method of claim 1 wherein in said step of attaching, electric current is applied to said electrodes in rectangular pulses of 5 to 10 milliamperes lasting for up to approximately 7 milliseconds at a rate of approximately 15 - 20 pulses per second.
- 3. The method of claim 2 wherein in said step of applying, the electromagnetic field is applied at a frequency of 300 kHz. and of an intensity to penetrate the body to a depth of approximately 15 cm.
- 4. The method of claim 3, wherein the step of introducing electrodes includes the step of folding over a bladder motor nerve the foil of an electrode having two platinum wires attached to a foil of insulating material tolerated by the body and covered with a similar insulating foil on two ends of each wire to leave a central area of each wire uncovered, the foil being folded over the nerve to bring the uncovered region of the wires into contact with the nerve.
- 5. An electrode for applying electrical stimulation to nerves, comprising, in combination:
 - a. a foil of flexible insulating material tolerated by the human body,
 - b. a pair of wires attached to one surface of said foil,
 - c. a first piece of similar insulating material attached to the foil to cover the two wires at one end of the foil, and
 - d. a second piece of insulating material attached to the other end of the foil to cover the two wires at the other end of the foil and leave the central region of both wires uncovered.
- 6. The combination defined in claim 5 in which said insulating material is polyethylene.

7. The combination defined in claim 6 in which said wires are platinum.

8. Apparatus for inducing artificial voiding of the bladder comprising, in combination:

- a. means for emitting outside of a human body an electromagnetic field having a high power of penetration into the human body, and having an oscillator supplying oscillations with a frequency of 300 kHz., a generator producing rectangular impulses in the range of 5 to 10 milliamperes, at a frequency in the range of 15 to 20 Hz., and having a duration of 7 milliseconds, modulator means for modulating the signal supplied by said oscillator as a function of the rectangular impulses produced by said generator, a power amplifier that receives and amplifies a signal from said modulator, and inductor which receives a signal from said modulator, and antenna means inductively coupled to said inductor for producing the electromagnetic field;
- b. A pair of electrical wires of a material tolerated by the human body;
- c. Receiver means for producing an electric current when stimulated by electromagnetic radiation, and being of a size to fit between the sacrum and the bladder of a human body and adapted to be mounted on the anterior wall of the sacrum, and being covered with a material tolerated by the human body, said resonant circuit having a coil with a tap; a first capacitor connected across said coil, detector means connected to the tap of said coil and to one of said electrical wires, the other of said electrical wires being connected to said coil and a second capacitor connected between said electrical wires to form a filter circuit; and
- d. electrodes mounted on said wires and adapted to be attached to pelvic nerves for applying electrical stimulation to the nerves, each electrode comprising, in combination:
 - i. a foil of flexible insulating material tolerated by the human body,
 - ii. a pair of wires attached to one surface of said foil,
 - iii. a first piece of similar insulating material attached to the foil to cover the two wires at one end of the foil, and
 - iv. a second piece of insulating material attached to the other end of the foil to cover the two wires at the other end of the foil and leave the central region of both wires uncovered.
- 9. The combination defined in claim 8 in which said detector means has a germanium diode.
- 10. The combination defined in claim 8 in which said receiver means is covered with polyethylene and said electric wires are made of platinum material.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,650,276

Dated March 21st, 1972

Inventor(s) Theodor Burghela, Vasile Ichim, Mihai Demetrescu

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

In the heading of the patent, line 7, change "Demetrescw" to --Demetrescu--. Column 2, line 22, change "(FIGS. 4 and 5)" to --(FIG. 3)--.

Signed and sealed this 3rd day of October 1972.

(SEAL)

Attest:

EDWARD M. FLETCHER, JR.
Attesting Officer

ROBERT GOTTSCHALK
Commissioner of Patents