

[54] URINARY CONTROL

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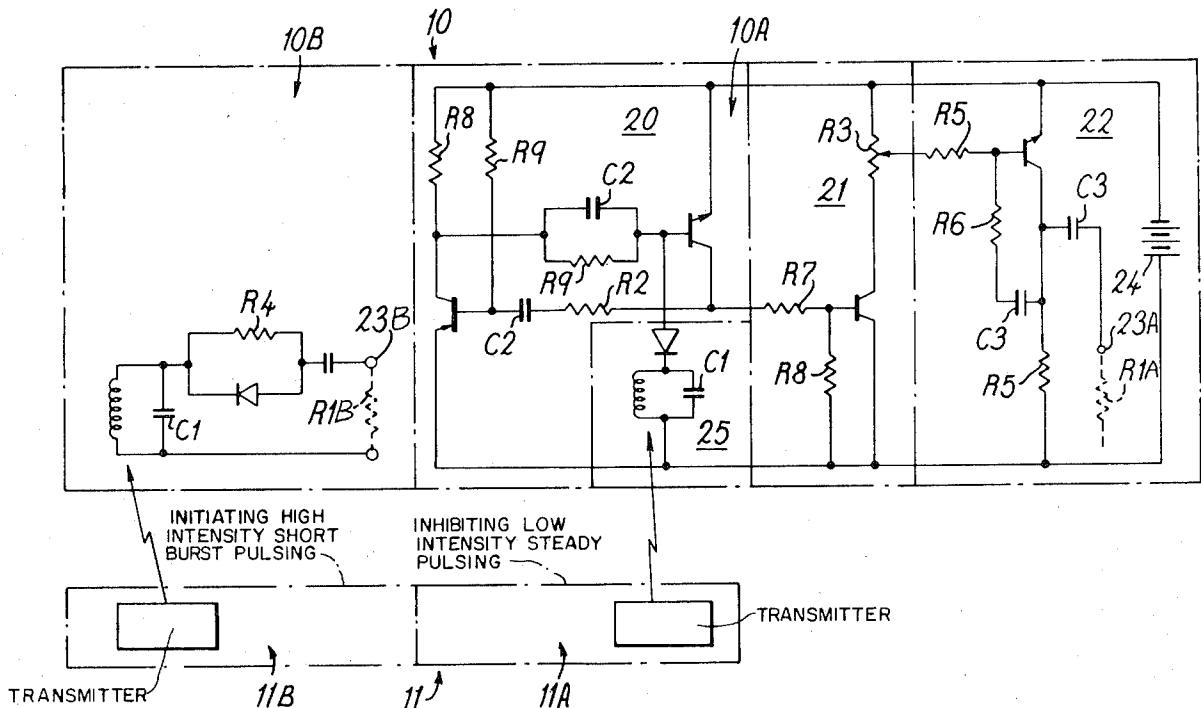
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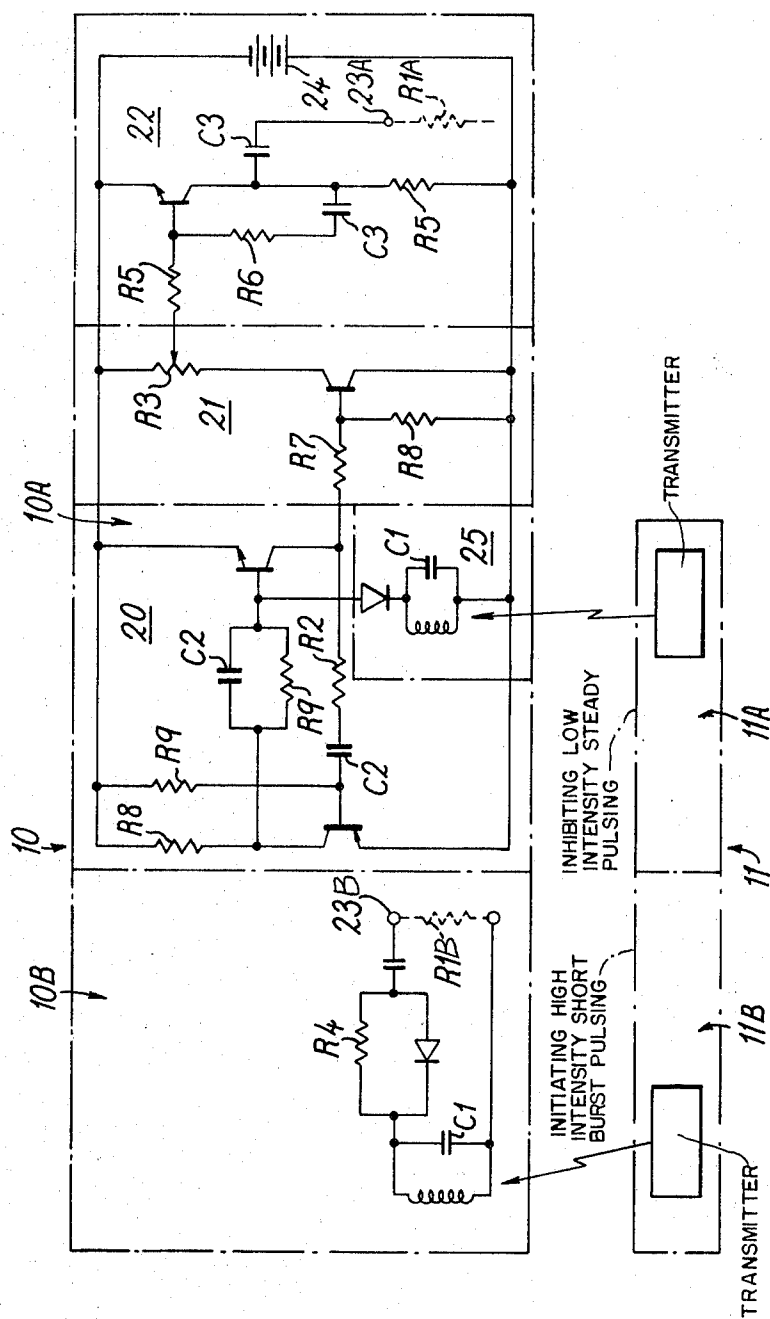
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[57] ABSTRACT

Urinary control by electrical stimulation of the sphincter and bladder muscles is effected by way of the sacral ventral roots, selection in the resultant muscle action being effected by use of discriminating signal forms. Sphincter closure action is effected by use of a low intensity pulse train whereby the sphincter is stimulated but not the bladder and so incontinence is avoided. Bladder muscle action to cause micturation is effected by use of a higher intensity pulse train whereby both muscles are stimulated during each pulse train, but during each interruption the sphincter relaxes while the bladder remains contracted.

12 Claims, 1 Drawing Figure





URINARY CONTROL

BACKGROUND OF THE INVENTION

This invention concerns urinary control and more particularly such control involving electrical stimulation by way of implanted electrodes. Also, the invention more particularly, but not exclusively, concerns urinary control for persons having disorders of neurological origin whereby they are unable to empty urine from the bladder by normal action of the bladder muscle, or unable to retain urine in the bladder by normal action of the sphincter, or, as is often the case, are unable to do either.

Various attempts have been made in the past to effect urinary control in the presence of such disorders by direct stimulation of appropriate muscles through electrodes implanted on the muscle to stimulate the associated motor nerve fibres. However, relatively large currents are required to effect the desired muscle contractions and, because the relevant motor nerve fibres are normally in close proximity with sensory fibres, stimulation is frequently associated with pain.

SUMMARY OF THE INVENTION

In a more general aspect, the present invention, on the other hand, affords similar urinary control by stimulation of the relevant muscles through electrodes implanted in the associated parts of the sacral ventral roots, normally numbers three and four, left and right. The muscles in question will be referred to hereinafter for convenience simply as the bladder muscle and the sphincter muscle. The former is intended to denote the detrusor muscle of the bladder, and the latter all of those striated muscles that contribute to closing the urethra. The principal one of these last muscles is the external sphincter of the urethra, but other pelvic muscles are also considered to be involved.

An advantage of the presently proposed control is that the sacral ventral roots are free from sensory fibres with the result that stimulation is unlikely to lead to pain. Also, it is more economic in terms of power requirements to stimulate the sacral ventral roots than the muscles directly or the motor nerve fibres in them.

However, the sacral ventral roots in question comprise tightly packed bundles including those which govern the activity of the bladder muscle and those which govern the activity of the sphincter muscle. Accordingly, unless it proves possible to separate the respective fibres, and this seems an impossible task on the basis of existing knowledge, it is necessary to adopt a mode of differential stimulation.

The invention involves one mode of differential stimulation which stems from the fact that the bladder muscle relaxes slowly after stimulation to contraction, while the sphincter muscle relaxes very rapidly in comparison. Thus, it is possible to stimulate the relevant fibres with electrical signals of interrupted form so that both muscles are contracted during each active signal period, while the bladder muscle remains contracted and the sphincter muscle is relaxed to afford micturition during at least a part of the signal interruption period. In practice each active signal will normally comprise a pulse train and the relevant interruption period is the inter-train interval.

Another mode of differential stimulation stems from the fact that the sacral ventral root fibres governing the activity of the bladder muscle are small compared to

those for the sphincter muscle, and it follows that the latter fibres are more sensitive to electrical stimulation than the former. Thus, it is possible to stimulate the fibres at an intensity which causes contraction of the sphincter muscle but not the bladder muscle. Again, this stimulation will normally involve the use of a pulse train signal.

It will be normal for the purposes of the earlier-mentioned more particular application of the invention to employ both of these modes of differential control with the second mode being employed to hold the sphincter normally contracted except when the first mode is employed to empty the bladder.

As clarification, useful mention can be made of practical development of the invention to date. This development has led to urinary control apparatus for which the normal or hold mode involves stimulation by application of a relatively low intensity pulse train signal having a pulse repetition rate of about twenty per second, and the micturition or empty mode involves stimulation by application of a relatively high intensity, interrupted pulse train signal in which each train comprises about twelve pulses in a relatively short burst each $1\frac{1}{2}$ seconds.

Regarding practical implementation of the invention: the power requirements for the two modes of stimulation are sufficiently low, namely, low intensity for long durations and high intensity for short durations, that implantation of suitable micro-circuits with battery power supplies is possible. However, it is necessary to provide some facility, controllable from without the body, to afford switching between the hold and empty modes of control. This can be effected by use of a radio transmitter/receiver arrangement as more generally described in U.S. Pat. No. 3,699,970 whereby an externally located transmitter is operated to energise an implanted receiver. Indeed, the use of such arrangements would allow both the hold and empty modes of control to be individually powered from without the body and so obviate the need for any implantation of power supplies.

In practice the present development has involved implementation with a compromise between these effective extremes of maximum and minimum implantation. In this compromise, the hold mode of control is provided by way of total implantation, and the empty mode by way of a transmitter/receiver arrangement which also serves to inhibit the hold mode. This overall arrangement is presently considered to represent an optimum in convenience to the beneficiary.

BRIEF DESCRIPTION OF THE DRAWING

For completeness in providing a clear understanding of the invention, one embodiment of the last-mentioned overall arrangement is illustrated, partly in diagrammatic form and partly in circuit diagram form, in the accompanying drawing. This embodiment has been successfully tested in animal trials with a baboon and is considered applicable to man.

DETAILED DESCRIPTION OF A PRESENTLY PREFERRED EMBODIMENT

The illustrated embodiment is in two parts denoted at 10 and 11 of which the first is implantable and the second employed externally of the body. Also these two parts 10 and 11 are themselves functionally subdivided into portions 10A, 10B and 11A, 11B, although

this subdivision does not necessarily involve physical separation.

The implantable portion 10A is the circuit which provides the hold mode of control referred to above and comprises a complementary multivibrator stage 20 operable to generate a pulse train of twenty pulses per second which are applied through a buffer stage 21 and output stage 22 to stimulating electrodes 23A. The electrodes 23A are located adjacent the relevant ventral sacral roots by use of electrode terminal devices such as described in U.S. Pat. No. 3,718,134 and the tissue load at the electrodes is denoted by broken line resistor R1A. This circuit is powered by a mercury cell 24, resistor R2 in the multivibrator stage is chosen so that fifty microsecond pulses are generated, and the potentiometer R3 affords adjustment of the output pulse intensity to a low level at which only the sphincter muscle is contracted. Potentiometer R3 is preferably adjustable post-operatively from without the body and this can be effected by use of a magnetic coupling.

The remaining components of the relevant circuit constitute an inhibiting stage 25 in the form of a simple radio receiver which is actuated in response to the external portion 11A to hold the multivibrator transistor switched off.

The implantable portion 10B is also of simple radio receiver form and serves, in response to the external portion 11B, to energise further stimulating electrodes 23B, in response to the external portion 11B.

As will be apparent from the above discussion, the external portions 11A, 11B are radio transmitters and it is unnecessary to consider more detailed circuit design since these portions can be of any suitable form to serve the relevant function requirements.

The more complex of these requirements is for the portion 11B which as mentioned earlier is to provide a relatively high intensity, interrupted pulse train signal. In the development in question the portion 11B comprised two multivibrators connected in cascade, with the first activating the second for a period of 120 milliseconds each $1\frac{1}{2}$ seconds, the second generating $12\frac{1}{2}$ millisecond pulses at $9\frac{1}{2}$ milliseconds separation during each period of activation, and the last-mentioned pulses gating the radio frequency output of the relevant transmitter.

The more simple requirement is for the portion 11A which is operated at the same time as portion 11B to provide a radio signal to inhibit the portion 10A.

Component values in the illustrated circuits are as follows:

R3 = 50K	R4 = 5K
R5 = 10K	R6 = 20K
R7 = 47K	R8 = 100K
R9 = 1M	C1 = 100p
C2 = 0.01μ	C3 = 1μ

While the invention has been described, and indeed developed so far, with reference to urinary control in respect of disorders of neurological origin, the invention may afford similar control in respect of disorders of non-neurological origin, such as urinary incontinence arising from gynaecological defects. By the same token, it will be appreciated that use of both of the above-discussed more specific modes of control is not essential in all applications of the invention.

We claim:

1. A method of urinary control which comprises applying an electrical signal of continuous pulse train form to the sacral ventral roots, said sacral ventral roots communicating with the sphincter muscle and bladder muscle, thereby causing the step of contracting said sphincter muscle while said bladder muscle is relaxed.

2. A method according to claim 1 wherein said pulse train has a pulse repetition rate of about 20 per second.

3. A method of urinary control which comprises applying an electrical signal of interrupted pulse train form to the sacral ventral roots, said sacral ventral roots communicating with the sphincter muscle and bladder muscle, thereby causing the step of contracting both of said muscles during each pulse train and the further step of maintaining said bladder muscle contracted during part of each interruption period between successive pulse trains when said sphincter muscle is relaxed.

4. A method according to claim 3 wherein said pulse trains are of short duration during successive intervals of about $1\frac{1}{2}$ seconds, and each comprise about twelve pulses.

5. A method according to claim 4 wherein each of said pulse trains comprises pulses of about $\frac{1}{2}$ millisecond duration each 10 milliseconds.

6. A method of urinary control which comprises alternatively applying two different pulsatile electrical signals to the sacral ventral roots, said sacral ventral roots communicating with the sphincter muscle and bladder muscle to thereby cause the step of stimulating said muscles, one of said signals being of lower intensity and higher repetition rate for causing the step of contracting said sphincter muscle while said bladder muscle is relaxed, and the other signal being of higher intensity and lower repetition rate for causing the step of contraction of both of said muscles during each pulse and to cause the further step of maintaining said bladder muscle contracted during part of successive inter-pulse periods when said sphincter muscle is relaxed.

7. A method of urinary control in primates, comprising:

applying pulsing electrical signals to the sacral ventral roots which control contraction of the detrusor muscle for the bladder and the striated, sphincter muscles which contribute to closing the urethra, in two different modes;

in the first of which, the signals are of a first intensity for the step of contracting the urethra closing muscles, but not contracting the bladder detrusor muscle, and including the step of spacing the first intensity pulses such that the urethra closing muscles do not become substantially relaxed between pulses; and

in the second of which, the signals are of a second intensity higher than said first intensity signals for causing the step of contracting both the urethra closing muscles and the bladder detrusor muscle, and including the step of spacing the second intensity pulses such that the urethra closing muscles, but not the bladder detrusor muscle become relaxed between pulses, such that pressure exerted on the bladder by the detrusor muscle in between pulses when the urethra closing muscles have relaxed, forces urine from the bladder and out through the urethra.

8. The method of claim 7, wherein the applying step comprises:

implanting in the subject primate:

- a. electrode means disposed for stimulating the third and fourth, left and right sacral ventral motor nerve fibre roots, without substantially stimulating sensory nerve fibres;
- b. multivibrator means and an electrical power supply therefor, for emitting said first intensity signals and a connection for communicating these signals to said electrode means;
- c. inhibiting means for preventing communication of said first intensity signals to said electrode means upon command;
- d. receiver means for receiving a command signal from outside the subject primate and connected to the inhibiting means for commanding same;
- e. multivibrator means for emitting said second intensity signals and a connection for communicating these signals to said electrode means;
- f. receiver means for receiving a command signal from outside the subject primate and connected to the multivibrator means to emit said second intensity signals;

wherein changing modes from the first to the second comprises: sending command signals from outside the subject primate to the receiver means of (d) and to the receiver means of (f); and

wherein changing modes from the second to the first comprises: terminating the sending of said command signals from outside the subject primate.

9. The method of claim 8, wherein: the implanted multivibrator means of (b) includes electrical output intensity adjustment means and the method further comprises: post operatively adjusting the intensity of signals provided by the implanted multivibrator means of (b) by adjusting the intensity adjustment means to ensure desired first mode operation wherein there occurs contraction of the striated, sphincter muscles which contribute to closing the urethra without substantially contracting the bladder detrusor muscle.

10. Urinary control apparatus comprising:

- a. stimulating electrode devices adapted for connection to the sacral ventral roots;
- b. a first electrical circuit means operable to generate a low intensity, continuous pulse train signal, which circuit means is connected to said electrode devices to energize the same;
- c. a second electrical circuit means operable to generate a high intensity, interrupted pulse train signal, which circuit means is connected to said electrode devices to energize the same; and
- d. means for alternatively activating said first and second circuit means to energize said electrode devices;
- e. said electrode devices and at least part of both said first and second circuit means being adapted for bodily implantation, and at least part of said activating means being for use outside the body.

11. Urinary control apparatus comprising:

- a. stimulating electrode devices adapted for connection to the sacral ventral roots;
- b. an implantable electric circuit means, including a power source, operable to generate a low intensity continuous pulse train signal, which circuit means is connected to said electrode devices to energize the same;

c. radio transmitter means for use outside the body operable to generate a first signal including at least a high intensity interrupted pulse train and a second signal;

d. an implantable first radio receiver means operable in response to said interrupted pulse train and connected to said electrode devices to energize the same; and

e. an implantable second radio receiver means operable in response to said second signal and connected to said electric circuit to inhibit operation of the same.

12. Apparatus for effecting urinary control in primates by applying pulsing electrical signals to the sacral ventral roots which control contraction of the detrusor muscle for the bladder and the striated, sphincter muscles which contribute to closing the urethra, in two different modes;

in the first of which, the signals are of a low intensity so as to contract the urethra closing muscles, but not to contract the bladder detrusor muscle, and wherein these low intensity signals are of such spacing between pulses that the urethra closing muscles do not become substantially relaxed between pulses; and

in the second of which, the signals are of a different intensity higher than said low intensity signals so as to contract both the urethra closing muscles and the bladder detrusor muscle, but of such spacing between pulses, that the urethra closing muscles, but not the bladder detrusor muscle become sufficiently relaxed between pulses, that pressure exerted on the bladder by the detrusor muscle in between pulses when the urethra closing muscles have relaxed, forces urine from the bladder and out through the urethra;

said apparatus comprising a surgical implant which includes:

- a. electrode means being disposed, when implanted, to stimulate the third and fourth, left and right sacral ventral motor nerve fibre roots, without substantially stimulating sensory nerve fibres;
- b. multivibrator means including an electrical power supply therefor, for emitting said low intensity signals and a connection for communicating these signals to said electrode means;
- c. inhibiting means for preventing communication of said low intensity signals to said electrode means upon the occurrence of a first command signal;
- d. receiver means for receiving the first command signal from outside the subject primate and connected to the inhibiting means for controlling same;
- e. multivibrator means for emitting said higher intensity signals and a connection for communicating these signals to said electrode means;
- f. receiver means for receiving a second command signal from outside the subject primate and connected to the multivibrator means of (e) for commanding and powering that multivibrator means to emit said higher intensity signals;

and said apparatus further comprising external transmitter means for sending said first and second command signals;

whereby, the sending of command signals from outside the subject primate to the receiver means of (d) and to the receiver means of (f) places urinary control in the second mode thereof and terminating the sending of said command signals places urinary control in the first mode thereof.

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