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(71) Applicant(s) Peter Ian Dawes 7 Westminster Court, ST ALBANS, Herts, AL1 2DU, United Kingdom	(56) Documents Cited GB 2123698 A EP 0620025 A1 EP 0391428 A1 EP 0336742 A1 EP 0087617 A1 US 5620483 A US 5559301 A US 4926865 A
(72) Inventor(s) Peter Ian Dawes	(58) Field of Search UK CL (Edition S) A5R RHAA RHAP RHAS INT CL ⁷ A61B , A61H , A61N ONLINE : WPI JAPIO EPODOC
(74) Agent and/or Address for Service Britter & Co Enterprise House, 14b Whitehorse Street, BALDOCK, Hertfordshire, SG7 6QN, United Kingdom	

(54) Abstract Title
Method of changing control parameters of a portable TENS device

(57) Medical apparatus, such as a portable TENS device 1 for pain relief, has a power source, a control means, command input means and electrical output means connected to patient skin electrodes. The command input means may comprise switches 10-13, which may have a toggle action, and dial 14, which may be a rotary digitally encoded potentiometer, and display panel 14. Setting an operating parameter of the device, such as the electrical output signal magnitude or frequency, may comprise the steps: firstly a respective toggle switch is pressed which allows signals to be accepted from the dial, secondly the dial is moved to set the required value of the parameter, thirdly the toggle switch is pressed again to cause the parameter value to be stored in a memory and subsequent motion of the dial is ignored. The display panel 14 may show if a parameter toggle switch has been pressed and may show the value of the parameter. The unit may have one or two output channels.

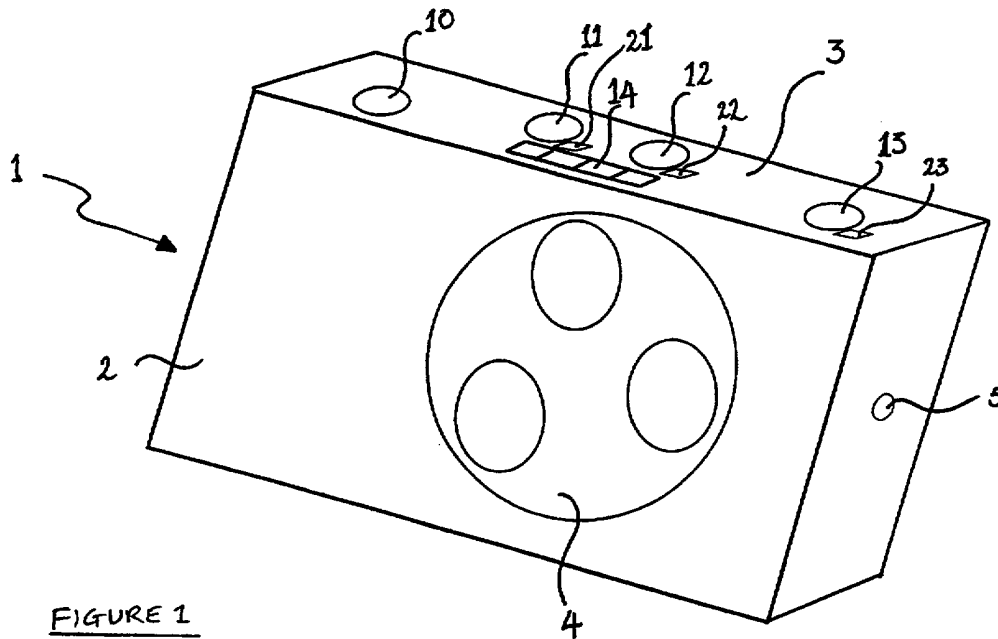
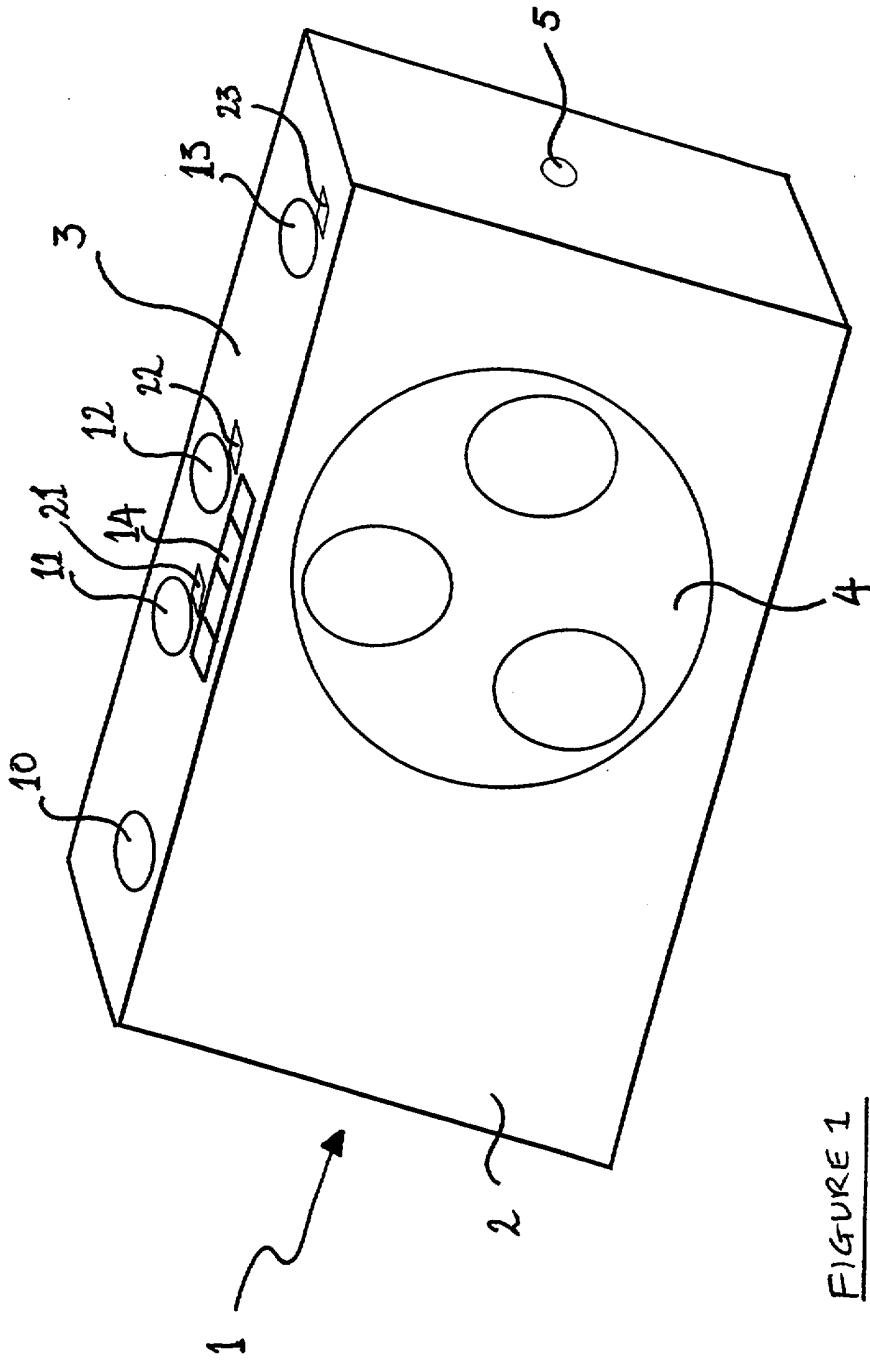


FIGURE 1

At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy. The claims were filed later than the filing date but within the period prescribed by Rule 25(1) of the Patents Rules 1995. This print takes account of replacement documents submitted after the date of filing to enable the application to comply with the formal requirements of the Patents Rules 1995



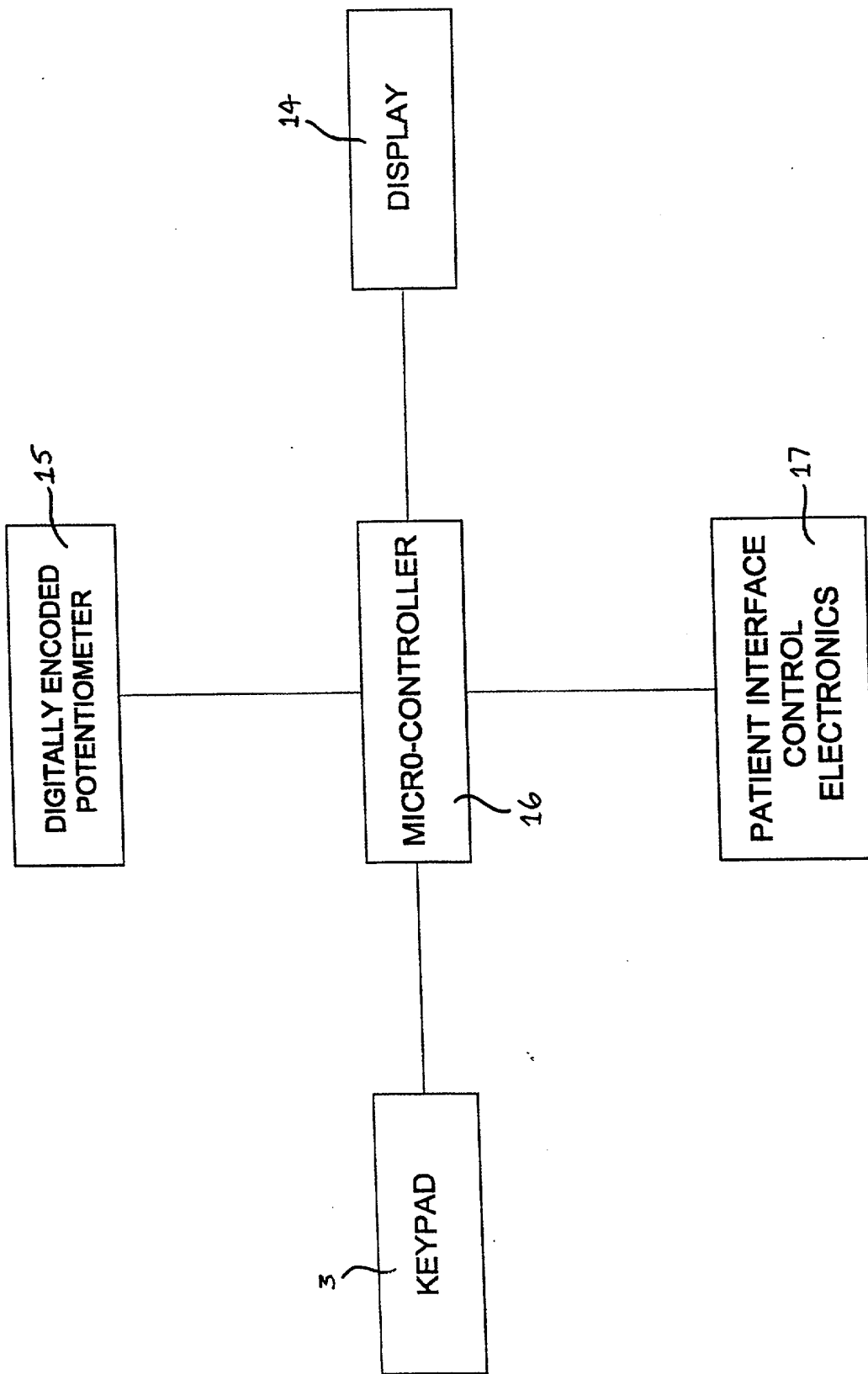


FIGURE 2

MEDICAL APPARATUSDESCRIPTION

5 This invention relates to medical apparatus, more specifically to
medical apparatus utilised in the treatment of pain by a sufferer.

 Pain is a warning signal generated by the body, normally in response to
a stimulus, and is interpreted by the brain as an injury or as illness. It provides
10 a natural warning system which is intended to prevent additional injury, and is
useful because without it body parts may continue to be damaged, without our
knowledge, until too late.

 Whilst most pains can be relieved by the administration of drugs
15 (analgesics), for example orally or topically, it is often the case that a medical
practitioner considers that an alternative control method is required. This is
usually because of a potential for side effects or other medical necessity, for
example a persistent user can become dependent on drugs and surgery carries
its own risks.

20 It has been known for a number of years that certain types of chronic
and acute pain can be relieved by the administration of electric impulses to the
skin. These techniques are known by the collective term electrogesics which
encompasses such treatments as Interferential Therapy (IT), Microcurrent
25 Electrical Nerve Stimulation (MENS) and Transcutaneous Electrical Nerve
Stimulation (TENS). As well as relieving the pain felt, such electrical
impulses may promote new cell growth and stimulate nerves. Additionally,
such techniques can result in a reduced post-operative recovery time and can
reduce the number of post-operative complications.

30 TENS works by administering small electrical pulses through a
patient's skin to underlying peripheral nerves. The application of electrical

stimuli to these nerves has at least two effects. Firstly, high frequency continuous, mild, electrical activity blocks or at least substantially inhibits the passage of any pain signal travelling to the brain. Secondly, low frequency electric signals promote beta endorphin release. These naturally occurring
5 pain-relieving molecules are produced in the body and help to regulate the pain sensation.

Therefore, TENS both prevents pain signals from reaching the brain and promotes pain-relieving chemical production within the body which may
10 provide additional relief for a period of time after the electrical stimulation has been removed. TENS represents a unique alternative method for the treatment of pain compared to conventional techniques.

TENS devices comprise a battery, potentiometer and electrode. The
15 potentiometer is varied to deliver a requisite electric signal to the electrode which is attached to the user's skin. The signal may be altered depending on the amount of pain being endured, obviously for larger amounts of pain the larger the signal required from the TENS device.

20 However, conventional TENS units have several drawbacks with regard to their functionality and usability. For example, the setting of each parameter may be difficult for a debilitated individual.

It is an object of the present apparatus to provide a TENS device which
25 has simplified controls such that its ease of use is vastly improved over previous devices.

According to the first aspect of the invention there is provided medical apparatus comprising a power source, control means, input means and output
30 means, wherein the control means is arranged to monitor the input means such that a first input allows a parameter to be set by the control means and a

second input causes that parameter to be stored, the stored parameter being directly related to an output at the output means.

5 According to a second aspect of the invention there is provided a medical apparatus for the administration of electrical signals comprising a power source, control means, input means and output means, wherein the input means is arranged to be monitored by the control means, such that a first input allows a parameter to be set by the control means and a second input causes that parameter to be stored, the stored parameter being directly related
10 to a component of an electrical signal at the output means.

Additionally, the input means and control means may be arranged to allow a set of parameters to be stored, each of which may be related to a component of the electric signal at the output means.

15

The output means may comprise one or more output channels. The signal at each of the output channels may comprise components which are identical or distinct.

20

Preferably the control means comprises a micro-controller and means to continuously vary the or each parameter. The varying means may be a potentiometer, which may be a resistive potentiometer, an optically encoded potentiometer or more preferably a digitally encoded potentiometer.

25

Additionally, the varying means or potentiometer may be manually controllable, such that any parameter is set to a value which is controlled manually and may be continuously variable.

30

The input means may comprise buttons, switches or dials which correspond to a parameter, activation of each button, switch or dial may allow the control means to vary the respective parameter. Each button, switch or dial

may, for example, allow the control means to vary one or more parameters. Each parameter may correspond to the frequency and/or the pulse width and/or the amplitude of the or each output signal.

5 The input means may further comprise indicia which may include a display panel. The panel may additionally comprise a portion which indicates a relative scale of the or each selected parameter.

10 The output may comprise a sinusoidal, rectangular, saw-tooth or square waveform, although the output preferably is a square or rectangular wave.

15 The output means may comprise an electrode which is attachable to a user. The output means may comprise a plurality of electrodes, each of which is attachable to a distinct location on a user. Each of the plurality of electrodes may deliver electric signals which have components which are identical or different.

20 The apparatus may be operable in continuous and/or modulated and/or pulsed output mode such that in continuous mode a constant output is generated, in modulated mode an output in which a component of the signal varies from, for example, a zero level to that determined by the stored parameter and in pulsed mode, a pulsed output is produced.

25 Additionally, the control means may be arranged to ignore the first input if, after a set time-period, a second input is not registered.

 Further, the apparatus may be portable, for example it may be pocket sized.

30

There is also provided a kit comprising a medical apparatus for the administration of electrical signals, a conductive gel and an adhesive tape.

5 The conductive gel is spreadable on the or each electrode to facilitate a conductive bridge between the or each electrode or output means and skin of a user, the or each electrode being fixable in place by the adhesive tape.

According to a third aspect of the invention there is provided a method of administering electrical signals comprising monitoring an input with a control means and, following a first input, setting a parameter with the control means and, following a second input, storing the parameter, and outputting an electrical signal which has a component directly proportional to the stored parameter.

15 In order that the invention may be more fully understood, preferred embodiments in accordance therewith will now be described, by way of example only, and with reference to the accompanying drawings in which:

Figure 1 shows a perspective view of the inventive apparatus; and
20

Figure 2 is a schematic diagram of the apparatus.

Referring to the Figures, there is shown a TENS apparatus, generally indicated at 1, comprising a casing 2, a keypad 3 which allows access to the functions of the apparatus, a rotary potentiometer controller 4 and an electrode interface port 5.
25

The keypad 3 consists of a series of switches 10 – 13 and a display panel 14. The switches comprise a power switch 10, a continual/burst toggle switch 11, a rate switch 12 and an output switch 13. The display panel 14 indicates the size of a selected parameter.
30

The apparatus 1 further comprises a digitally encoded potentiometer 15 and a micro-controller 16 which monitors and controls the functions set by operation of the keypad 3. An electrode (not shown) is interfaced with the apparatus at the interface port 5.

In use, a suitably interfaced electrode, with associated control electronics (Figure 2) is attached to the area of treatment on a patient, the conductive bridge between patient and electrode being facilitated by a conductive gel. The electrode is attached to the patient by, for example, an adhesive tape which may be of hypoallergenic nature. Alternatively a self-adhesive electrode can be used to obviate the need for adhesive tape.

An array of different electrodes may be used by a user, depending on the particular site of pain and the type of treatment required. Each electrode is applied to clean dry skin to provide a good contact therebetween.

The patient activates the apparatus by operating the power switch 10 at which point the micro-controller 16 scans the keypad 3 for switch operation. When a switch is pressed, for example the rate switch 12, the micro-controller 16 generates a signal which activates and controls the display panel 14 and activates a light 22 to indicate that the micro-controller 16 is controlling the input of that parameter.

By turning the rotary potentiometer controller 4, the rate, or more accurately the frequency, of output signal at the electrode is controlled. The magnitude of the frequency is displayed on the display panel 14. When the rate switch 12 is pressed again the micro-controller 16 disengages the rotary controller 4, the frequency selected is stored and the micro-controller 16 extinguishes the display panel 14. Any subsequent movement of the rotary controller 4 is ignored.

The patient then presses, for example, the output switch 13, at which point the micro-controller 16 generates a signal to control the display panel 14, lights the light 23 and accepts signals from the rotary controller 4. The rotary controller 4 is then adjusted so that the output or, more accurately, the amplitude of the signal at the electrode is varied to a suitable magnitude. The relative size of the amplitude of the signal is displayed on the display panel 14.

When this switch 13 is pressed again, the micro-controller 16 stores the required amplitude and any subsequent movement of the rotary controller 4 is ignored.

The frequency of output may be continuously varied from 1 to 200 hertz, although this may be restricted in normal use to vary from 2 to 150 hertz and the output current may be continuously varied from 0 to 50 mA. The waveform is preferably an asymmetrical bi-phasic square wave although other waveforms can be used such as sinusoidal, saw-tooth etc.

Once the parameters have been set and stored within the apparatus 1, it may be configured to provide a continual operation or a pulsed operation. Pressing the pulse switch 11 toggles the apparatus 1 between these configurations and the operating condition is indicated at an associated light 21 which is controlled by the micro-controller 16. In pulsed operation, the light 21 flashes and the apparatus 1 can deliver nine pulses of 150 hertz signal which is repeated every half a second.

The apparatus 1 is provided with a time-out feature such that if thirty seconds after a switch has been pressed and there is no movement of the rotary controller 4 the pressed switch, for example 12, will be deselected and its associated light, for example 22, will be extinguished. Any subsequent movement of the rotary controller 4 will be ignored.

The apparatus 1 is powered by a small low voltage battery, such as a 9V PP3 battery, which is carried inside the casing 2 of the apparatus 1. A transformer converts the output of the battery to the requirements of the apparatus 1.

The switches 10 to 13 are all provided with a toggle action which, coupled with the micro-controller 16 and rotary controller 4, afford the inventive apparatus 1 ease of operation and control. A patient may increase or decrease the frequency and output as required or as instructed by a medical practitioner.

In a further embodiment, the apparatus 1 may be provided with two or more interface ports 5, such that more than one electrode may be interfaced to the unit.

For example, if the apparatus were provided with two interface ports, and consequently had two electrodes interfaced thereto, the parameters for the first electrode are set as described above. In order to set the parameters for the second output the same procedure is carried out, although for the micro-controller 16 to allow a parameter to be set, the button 11, 12 or 13 must be pressed twice in quick succession. This has the effect of illuminating the respective light 21, 22 or 23 in red to indicate that the second output parameters are being set.

In apparatus which has single channel output, or in apparatus with multi-channel output, a parameter corresponding to the pulse width of the output signal(s) may be varied. In this instance either a further input button is provided and the pulse width is controlled in an identical fashion to the frequency and amplitude or one of the buttons 11, 12, 13 is multi-functional.

If the button 11, 12, 13 is multi-functional pushing it a certain number of times in quick succession will indicate to the micro-controller 16 that the pulse width parameter needs to be set. In such a case the light associated with the button is illuminated a distinctive colour. The pulse width may be varied,
5 for example, between 20 and 300 μ s as required by a user.

In a further embodiment, the switch 11 may be configured as a continual/modulated/burst toggle switch. Modulated operation allows a or all of the components of the or each electrical signal to alter from a pre-set level
10 to the level set by the user in the normal fashion. For example, the amplitude and frequency of a channel may be linearly increased from zero to the level determined by the patient, although it may be configured for exponential rather than linear alteration.

15 The lights on the display panel 14 and the lights 11, 12, 13 may be either LED's or LCD's as is well known in the art. Furthermore, it is not necessary to utilise a transformer and low voltage battery, indeed any means known in the art may be employed to provide the required high voltages.

20 The apparatus 1 may be provided with a clip in order that it may be worn on a belt. In such a situation, the electrodes may be left in place whilst the user carries out his or her normal duties or business. The lead wires which connect the electrode to the apparatus comprise a resilient, flexible, insulated material which provides a durable connection.

25

Therefore, it can be seen that the apparatus provides a safe and easy to use TENS apparatus which may be used without fear of exposing a patient to too large a signal and which is continuously variable, within its operating limits, to provide a patient with the widest possible treatment regime.

CLAIMS

1. Medical apparatus comprising a power source, control means, input means and output means, wherein the control means is arranged to monitor said
5 input means such that a first input allows a parameter to be set by said control means and a second input causes that parameter to be stored, the stored parameter being directly related to an output at said output means.

2. Medical apparatus for the administration of electrical signals comprising a
10 power source, control means, input means and output means, wherein said input means is arranged to be monitored by said control means, such that a first input allows a parameter to be set by said control means and a second input causes that parameter to be stored, the stored parameter being directly related to a component of an electrical signal at said output means.

- 15 3. Apparatus according to claim 1 or 2, wherein said input means and control means are arranged to store a set of parameters.

4. Apparatus according to claim 3, wherein each parameter of the set of
20 parameters is related to a component of the electric signal at said output means.

5. Apparatus according to any preceding claim, wherein said output means comprises one or more output channels.

- 25 6. Apparatus according to claim 5, wherein the output or signal at each of the output channels comprise components which are identical.

7. Apparatus according to claim 5, wherein the output or signal at each of the
30 output channels comprise components which are distinct.

8. Apparatus according to any preceding claim, wherein said control means comprises a micro-controller and means to continuously vary the or each parameter.
- 5 9. Apparatus according to claim 8, wherein said varying means is a potentiometer.
- 10 10. Apparatus according to claim 9, wherein the potentiometer is one of a resistive potentiometer, an optically encoded potentiometer and a digitally encoded potentiometer.
- 15 11. Apparatus according to claim 8, 9 or 10, wherein said varying means or potentiometer is manually controllable, such that a parameter is set to a value which is controlled manually.
- 20 12. Apparatus according to any of claims 8 to 11, wherein any parameter which is set by said varying means is continuously variable.
- 25 13. Apparatus according to any preceding claim, wherein said input means comprises buttons, switches or dials which correspond to a parameter, activation of each button, switch or dial allowing the control means to vary the respective parameter.
- 30 14. Apparatus according to claim 13, wherein each button, switch or dial allows the control means to vary one or more parameters.
15. Apparatus according to any preceding claim, wherein the or each parameter corresponds to the frequency and/or the pulse width and/or the amplitude of the or each output or signal.

16. Apparatus according to any preceding claim, wherein said input means further comprises indicia, for example a display panel.
17. Apparatus according to claim 16, wherein the panel comprises a portion
5 which indicates a relative scale of the or each selected parameter.
18. Apparatus according to any preceding claim, wherein the output or signal comprises a sinusoidal, rectangular, saw-tooth or square waveform.
- 10 19. Apparatus according to claim 18, wherein the output or signal is a square or rectangular wave.
20. Apparatus according to any preceding claim, wherein said output means comprises an electrode which is attachable to a user.
- 15 21. Apparatus according to any preceding claim, wherein said output means comprises a plurality of electrodes, each of which is attachable to a distinct location on a user.
- 20 22. Apparatus according to claim 21, wherein each of the plurality of electrodes delivers electric signals which have components which are identical or different.
- 25 23. Apparatus according to any preceding claim which is operable in continuous and/or modulated and/or pulsed output mode such that in continuous mode a constant output is generated, in modulated mode an output in which a component of the signal varies from, for example, a zero level to that determined by the stored parameter and in pulsed mode, a pulsed output is produced.

24. Apparatus according to any preceding claim, wherein said control means is arranged to ignore the first input if, after a set time-period, a second input is not registered.
- 5 25. Apparatus according to any preceding claim, wherein the apparatus is portable, for example it may be pocket sized.
26. A kit comprising a medical apparatus for the administration of electrical signals in accordance with claim 2 or any claim dependent thereon, a
10 conductive gel and an adhesive tape.
27. A kit according to claim 25, wherein the conductive gel is spreadable on the or each electrode to facilitate a conductive bridge between the or each electrode or output means and skin of a user, the or each electrode being
15 fixable in place by the adhesive tape.
28. A method of administering electrical signals comprising monitoring an input with a control means and, following a first input, setting a parameter with the control means and, following a second input, storing the
20 parameter, and outputting an electrical signal which has a component directly proportional to the stored parameter.
29. Medical apparatus substantially as hereinbefore described and with reference to the accompanying drawings.
25
30. A kit substantially as hereinbefore described and with reference to the accompanying drawings.
31. A method substantially as hereinbefore described and with reference to the
30 accompanying drawings.



INVESTOR IN PEOPLE

Application No: GB 9919721.2
Claims searched: 1 to 30 only

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Examiner: Gareth Lewis
Date of search: 6 March 2001

Patents Act 1977 Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK CI (Ed.S): A5R RHAA RHAS RHAP

Int CI (Ed.7): A61N A61B A61H

Other: Online : WPI JAPIO EPODOC

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
X	GB 2123698 A (BIOSTIM) See figure 6 and columns 2 and 3	1 to 8, 11 to 16, 20 to 23, 25, 28
X	EP 0620025 A1 (ELECTRO SCIENCE) See abstract	1, 2, 28 at least
X	EP 0391428 A1 (OMRON) See abstract and all figures	1, 2, 28 at least
X	EP 0336742 A1 (BRISTOL MYERS) See abstract	1, 2, 28 at least
X	EP 0087617 A1 (SIEMENS) See abstract	1, 2, 28 at least
X	US 5620483 (BMR) See abstract	1, 2, 28 at least
A	US 5559301 (KORG) See whole document especially abstract and figures 10a-f.	
X	US 4926865 (OMAN) See abstract	1, 2, 28 at least

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.



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Category	Identity of document and relevant passage	Relevant to claims

X Document indicating lack of novelty or inventive step	A Document indicating technological background and/or state of the art.
Y Document indicating lack of inventive step if combined with one or more other documents of same category.	P Document published on or after the declared priority date but before the filing date of this invention.
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