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[54] **METHOD FOR OBTAINING NEUROPHYSIOLOGICAL EFFECTS**

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[51] **Int. Cl.** **A61n 1/36**

[58] **Field of Search**........ 128/419 R, 420, 421, 422, 128/1 C

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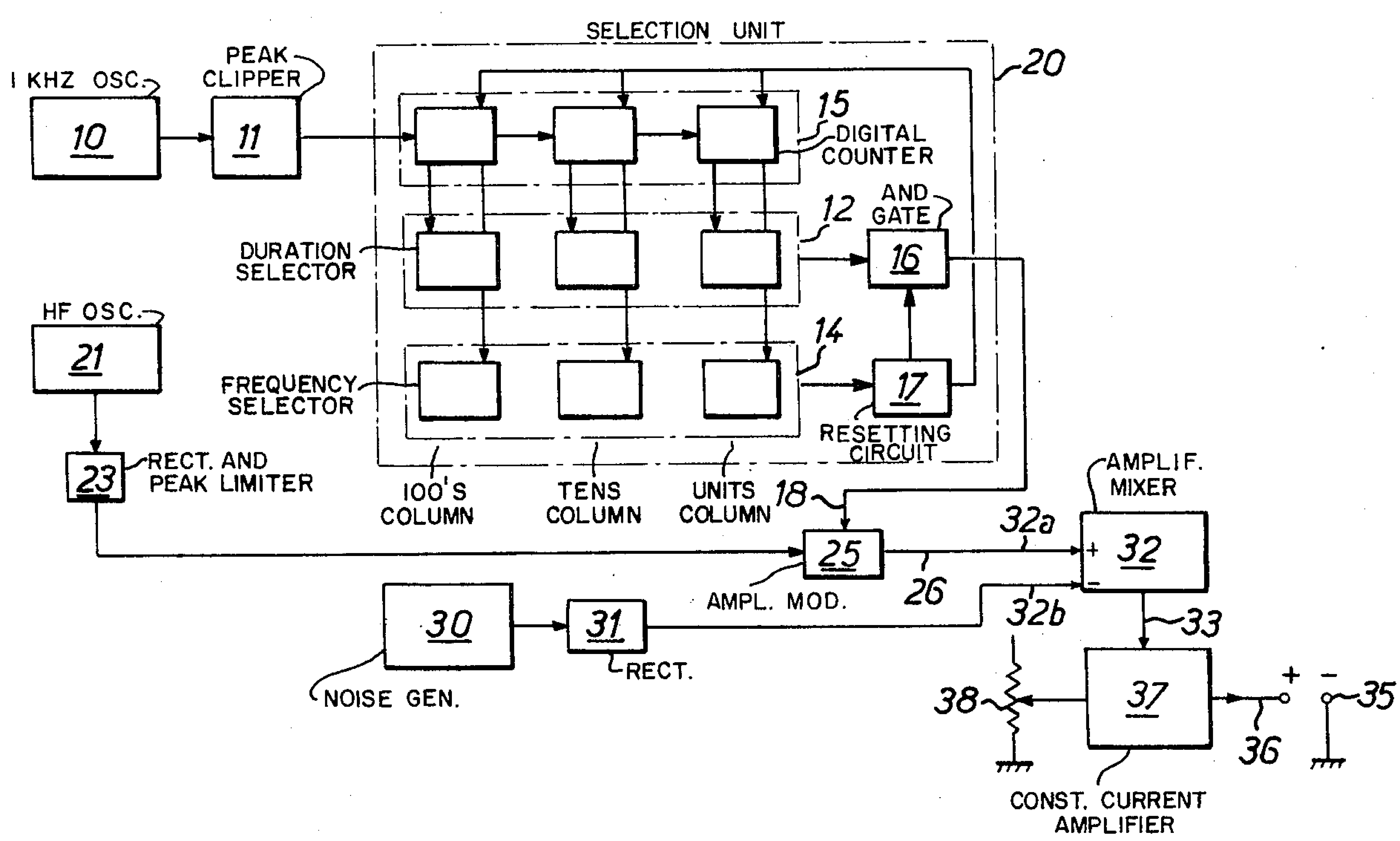
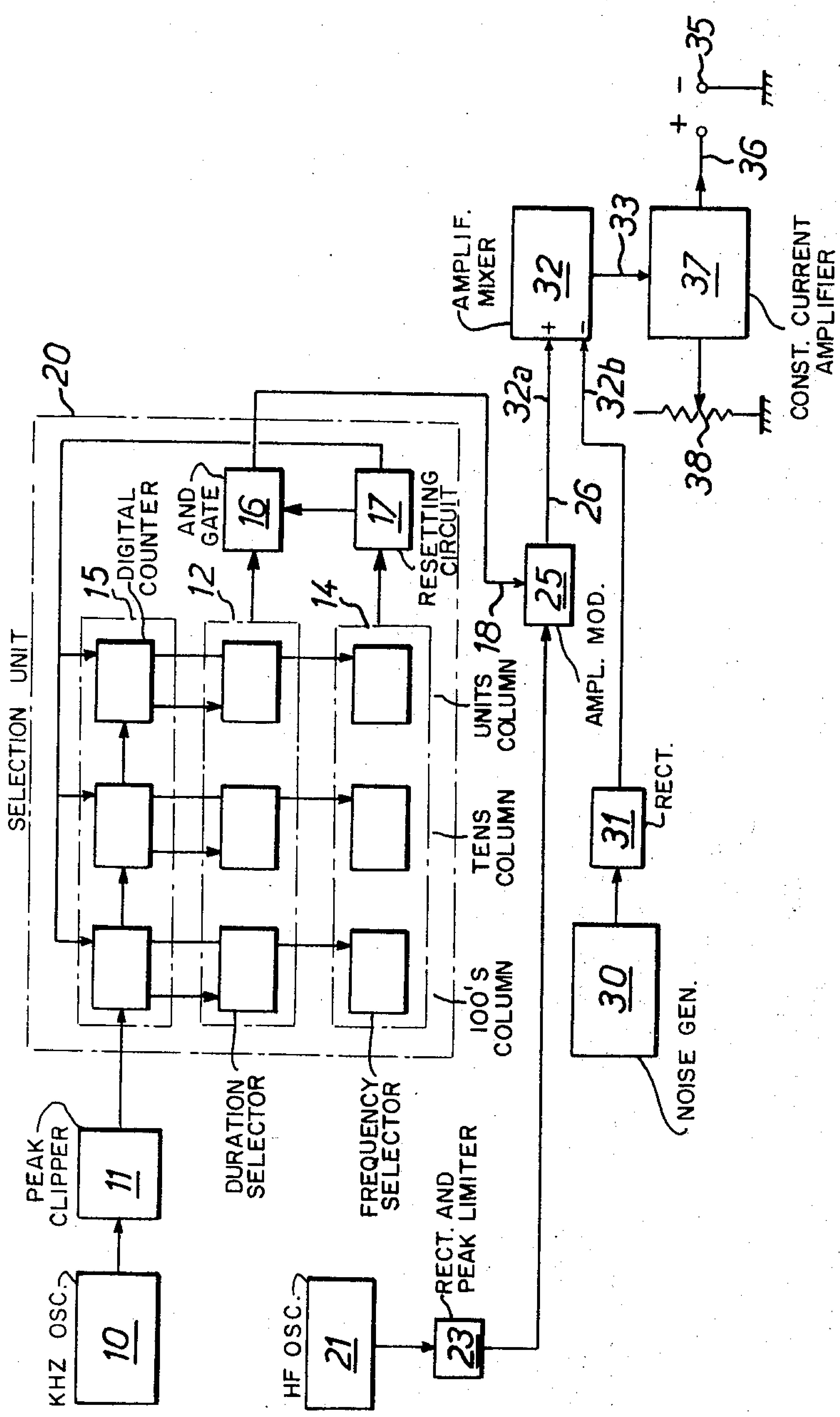
[57] **ABSTRACT**

A method and apparatus for obtaining neurophysiological effects on the central and/or peripheral systems of a patient. Electrodes are suitably positioned on the body of the patient and a composite electric signal is applied at the electrodes. The composite signal is formed by the superpositioning of two signals: a first signal which is a rectified high-frequency carrier modulated in amplitude to about 100 percent by substantially square-shaped pulses whose duration, amplitude and frequency are chosen according to the neurophysiological effects desidered, and a second signal which has a relatively white noise spectrum. The mean value of the first electric signal has a predetermined sign which is opposite the sign of the mean value of the second electric signal.

5 Claims, 1 Drawing Figure




1 KHZ OSC.
10
PEAK CLIPPER
11
SELECTION UNIT
20
15
DIGITAL COUNTER
12
DURATION SELECTOR
14
FREQUENCY SELECTOR
AND GATE
16
17
RESETTING CIRCUIT
UNITS COLUMN
TENS COLUMN
100'S COLUMN
18
HF OSC.
21
RECT. AND PEAK LIMITER
23
25
AMPL. MOD.
26
30
NOISE GEN.
31
RECT.
32a
32b
32
AMPLIF. MIXER
33
37
CONST. CURRENT AMPLIFIER
38
36
35

METHOD FOR OBTAINING NEUROPHYSIOLOGICAL EFFECTS

BACKGROUND OF THE INVENTION

The present invention concerns a method and apparatus for obtaining neurophysiological effects by the application of electric currents to the central and/or peripheral nervous systems of the human body.

It is known that the application of electrical signals at electrodes placed at suitably chosen points on the body of a patient is capable of causing various effects such as general or local anaesthesia, sleep or relaxion of the subject depending on the location of the electrodes and the parameters defining the signal.

Among the various types of signals for obtaining such results, it has been established that the use of square-shaped pulses of suitable amplitude, frequency and period is particularly effective.

Such signals, may, however, cause bothersome secondary phenomena such as contractures, polarization or electrolysis effects which could be redhibitory in numerous cases.

With regard to these drawbacks, it has been proposed to use for similar applications a complex signal consisting of a rectified high-frequency signal which is about 100 percent amplitude modulated by low frequency square-shaped pulses which in the majority of cases enables the total elimination of the contractures remaining when the low frequency pulses shapes a direct current signal instead of the envelope of a rectified high frequency signal.

The effects so obtained are clearly superior to those of the former technique. Nevertheless, the rectified high-frequency signals modulated by low-frequency square-shaped pulses is not entirely satisfactory in all applications, because they do not enable the complete elimination of undesirable phenomena such as local electrolysis, disagreeable tingling or other unacceptable reactions necessitating the reduction of the current of the applied signals or the shortening of the length of application thereof.

SUMMARY OF THE INVENTION

The present invention enables the reduction or even the complete elimination of undesirable secondary effects by reducing the mean value of the currents applied on which the said secondary effects directly depend, without substantially reducing the desired principal neurophysiological effects.

To this effect, the present invention provides a method for obtaining neurophysiological effects on the central and/or peripheral nervous systems of a patient, comprising positioning electrodes on the body of the patient, applying a composite electric signal at the electrodes formed by the superpositioning of a first and second electric signal, said first electric signal being a rectified high-frequency carrier modulated in amplitude to about **100** percent by substantially square-shaped pulses whose duration, amplitude and frequency are chosen according to the desired neurophysiological effects, the mean value of said first electric signal being of a predetermined signal said second signal having a relatively white noise spectrum, the sign of the mean value of said second electric signal being opposite that of the mean value of said first electric signal.

The white noise constituting the said second signal may have a substantially continuous spectrum ranging from 1 KHz to 60 KHz and preferably between **20** and **60** KHz. Such a noise signal could be easily obtained by means of a gas discharge tube, a semi-conductor or other appropriate means.

As previously indicated, it has been observed throughout that the undesirable secondary effects of electrophysiological treatment are all the more accentuated when the average current passing through the electrodes applied to the body of the patient is increased.

In the method according to the invention, this average current intensity, whose value is the algebraic sum of the respective mean values of said first and second signals, is the difference between these mean values.

I was surprised to find that the presence of white noise which enables the reduction of the overall mean current strength, the electrolysis effects and the intolerance of the body, remains without any detriment to the effectiveness of the treatment. It is thought that this very advantageous property comes from the fact that the relatively continuous spectrum of the white noise signal avoids the generation of undesired possibly detrimental discrete beat frequencies from the pulse modulated carrier and the white noise signal, while being capable of bringing about by an appropriate choice of the limits of this continuous spectrum complementary neurophysiological effects resulting in a renforcement of the principal desired effect.

According to the intended application, the relative proportion of the noise component and the modulated high-frequency component may be advantageous between one-fourth and one-half in the majority of cases, this proportion designating the ratio of the mean current strength of these components.

The method according to the invention is particularly applicable to obtaining neurophysiological effects such as relaxation, sleep, general analgesia, local-regional anaesthesia, and general anaesthesia.

Its use is particularly advantageous when the current strength of the pulse modulated high-frequency signal whose average value is the product of the r.m.s. value of the high-frequency carrier by the mark-to-space ratio of the square-shaped low-frequency pulses must be rather large, as for example in the case of electro-analgesia or electro-anaesthesia treatments.

Also disclosed is a device for carrying out the method described above comprising a high-frequency signal generator, a low-frequency pulse generator, means for modulating the amplitude of the said high-frequency signals by the low-frequency pulses, a noise generator adapted to generate electric signals having a relatively continuous frequency spectrum and mixing means adapted to superimpose the modulated high-frequency signal generated by said modulation means and the signals from the noise generator for providing a composite signal with a mean amplitude proportional to the difference between the respective mean amplitudes of the modulated high-frequency signal and said noise signal.

Preferably, the apparatus comprises control means selectively adjusting certain or all parameters defining the composite output signal, i.e., the peak amplitude of the modulated high-frequency signal, the amplitude of the noise signal, the frequency of the high-frequency signal, the length and the spacing of the low frequency modulation pukes, as well as the spectrum of the signal delivered by the noise generator.

Suitable switching means may be advantageously provided to make available one or more elementary signals utilised to generate the above-defined composite signal at one of the outputs of the device. Indeed, it could be advantageous in certain electro-neurophysiological treatments to combine the application of composite signals according to the invention with signals of different characteristics simultaneously or sequentially with the composite signals, and it is therefore advantageous to provide a single device to generate these different signals.

BRIEF DESCRIPTION OF THE DRAWINGS

The features and avantages of the present invention will be brought out in the description made herein by way of the example with reference to the accompanying drawing illustrating schematically a device according to the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The device illustrated in the drawing comprises a low-frequency square pulse generator channel driven by an oscillator **10** having 1 KHz frequency whose output signal after shaping by peak clipper **11** or other circuit adapted to generate straight-sided signals is applied to a selection unit **20** enabling the formation of low-frequency pulses whose length and frequency may be displayed by manual selectors **12** and **14** with three digits corresponding to units, tens and hundreds of the quantity displayed. These selectors are associated with the corresponding decimal stages of a digital counter **15** fed by the pulses issued from the peak clipper **11.**

The width of the pulses available at the output **18** of the unit **20** is determined by the length of the conducting of an AND gate **16** controled by the selector **12,** whereas the time interval between successive resettings of the counter **15** is determined by the selector **14** which acts to this end on the resetting circuit **17.** On each resetting the resetting circuit causes the AND gate **16** to open. Thus at the output **18** there is a substantially square-shaped low-frequency pulse the width and period of which may vary by steps of 0.5 and 1 millisecond as a function of the adjustment of the selectors **12** and **14.**

The pulses thus obtained amplitude modulate a high-frequency signal generated by an oscillator **21** whose frequency is adjustable, for example, between 100 KHz and 1 MHz. This signal passes through a rectifier peak-limiter **23** adapted to rectify one or both of the high-frequency half-cycles then is applied to an amplitude modulator **25** at the output **26** of which are available high-frequency signals whose envelope comprises the low-frequency pulses and whose polarity is constant owing to the prior rectification of the high-frequency carrier. Preferably, the degree of modulation is 100 percent; to this end the modulator could comprise an AND gate having inputs connected, as shown in the drawing, to the output **18** of the unit **20** and the output of the rectifier peak-limiter **23.**

The device according to the invention comprises a noise generator **30** whose output signal after rectification is intended to be one of the two components of the output signal of the device. The generator **30** may be, for example, a suitable gas filled tube (not shown) or other means adapted to generate random signals in a relatively continuous spectrum. Preferably, these signals have a spectrum between 1 KHz and 60 KHz and a relatively uniform spectral distribution, such a distribution defining the signals which have been hereinabove referred to as "relatively white noise signals." This spectrum may, for example, be defined by means of a suitable band-pass filter (not shown) which may be adjustable.

The signal generated by the noise generator **30** is rectified by a rectifier **31** over one or two half-cycles, and are then subtractively mixed with the modulated high-frequency signal available at the output of the modulator **25** by an amplifier-mixer **32** so as to obtain a composite signal having a mean current strength proportional to the difference of the mean current strength of its components.

Accordingly, the amplifier **32** may comprise an input stage (not shown) constituted by a differential amplifier having direct and reversed inputs **32*a*** and **32*b*** respectively connected to the output **26** of the modulator **25** and the output of the rectifier **31** through the intermediary of level adjusting means adapted to enable the adjustment of the relative proportion of the modulated high-frequency signal and the noise signal constituting the two components of the signal available at the output **33** of the amplifier-mixer **32** which comprises a final stage (not shown) adapted to provide the desired power of the composite signal obtained.

The electrodes for applying the composite signal to the patient are connected to two outputs terminals of the device, the electrode **35** of which is connected to the case of the apparatus whereas the other electrode **36** is connected to the output **33** through the intermediary of a constant current amplifier **37** associated with current adjusting means schematically respresented by a potentiometer **38.**

The constant current amplifier **37** may comprise a circuit having an output impedance sufficiently large so as to provide an output current which only slightly varies with respect to changes in the load resistance formed by the portion of the body of the patient situated between the points of application of the electrodes.

As indicated above auxiliary outputs (not shown) may be provided for making available if necessary pure low-frequency pulses, non-modulated high-frequency signals, noise signals or even a D.C. component.

What I claim is:

1. A method for obtaining neurophysiological effects on the central and/or peripheral nervous systems of a patient, comprising generating a high-frequency carrier, rectifying the high-frequency carrier, generating substantially square-shaped pulses whose duration, amplitude and frequency are chosen according to the desired neurophysiological effect, amplitude modulating to about 100 percent the rectified high-frequency carrier with said pulses thereby producing a first electric signal, generating a relatively white noise spectrum signal, rectifying the relatively white noise spectrum signal thereby producing a second electric signal, the sign of the mean value of the second electric signal being opposite that of the mean value of said first electric signal, superposing said first and second electric signals to produce a composite electric signal having an average amplitude which is the difference between the average amplitude of said first and second electric signals, positioning electrodes on the body of the patient, and applying said composite electric signal at the electrodes.

2. A method according to claim **1**, wherein said first and second signals each have polarities which are constant as a function of time.

3. A method according to claim **1**, wherein the spectrum of the said relatively white noise is between 1 KHz and 60 KHz.

4. A method according to claim **3**, wherein the spectrum of said relatively white noise is between 20 and 60 KHz.

5. A method according to claim **1**, wherein the ratio between the mean current strength of said second signal and the mean current strength of said first signal is between one-fourth and one-half.

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