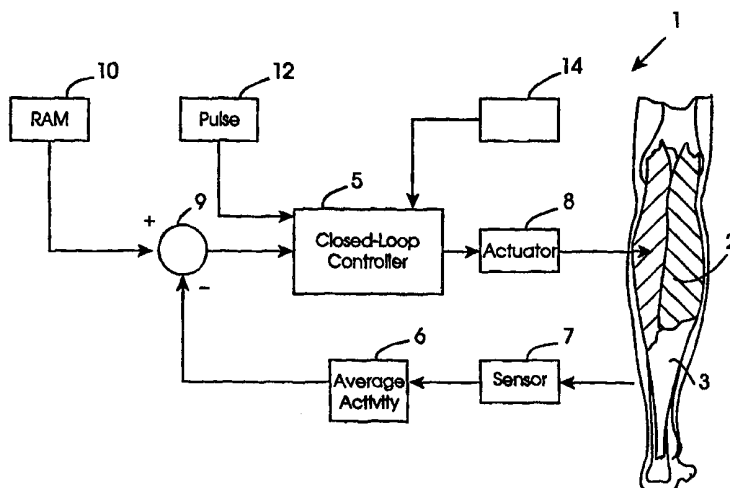




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(54) Title: APPARATUS FOR IMPROVING MUSCLE PUMP ASSISTED BLOOD FLOW, AND A METHOD FOR IMPROVING MUSCLE PUMP ASSISTED BLOOD FLOW

**(57) Abstract**

Apparatus (1) for improving muscle pump assisted blood flow in a calf muscle (2) of a leg (3) of a subject comprises an actuator (8) for attaching to the calf muscle (2) for stimulating the calf muscle (2) for in turn stimulating muscle pump activity in the calf muscle (2). A muscle pump activity sensor (7) attached to the leg (3) of the subject adjacent the calf muscle (2), which may be provided by an accelerometer monitors the muscle pump activity. An averaging circuit (6) averages muscle pump activity over a predetermined time period, which is compared in a comparator (9) with a threshold value of desired activity stored in RAM (10). The output from the comparator (9) is fed to a controller (5) which activates the actuator (8) for stimulating muscle pump activity in the event that the average monitored muscle pump activity is less than the threshold value. A pulse sensor (12) monitors the pulse of the subject so that the actuator (8) is activated in synchronisation with the arterial pump of the subject.

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"Apparatus for improving muscle pump assisted blood flow, and a method for improving muscle pump assisted blood flow"

The present invention relates to apparatus for improving muscle pump assisted blood flow in a subject, which may be an animal or human subject, and in particular, for improving such blood flow in a limb of a subject, for example, a lower leg. The invention also relates to a method for improving muscle pump assisted blood flow in a subject.

Poor blood circulation in a subject, in general, tends to manifest itself at the peripheral portions of the body, typically, the distal part of the limbs, such as, for example, the lower leg. Arterial blood pressure in a subject tends to fall off the further one moves from the heart, and because of this, poor circulation begins to manifest itself, initially, in the lower leg and other distal regions of the body.

However, in the lower leg, and indeed, other limbs, the circulatory process is assisted by what is generally referred to as a muscle pump. In the lower leg, this is referred to as the calf muscle pump. The calf muscle pump, and indeed, other muscle pumps act on blood flow as the muscle contracts and relaxes. Blood circulates through a venous network which is embedded in the muscles. A series of valves located in blood vessels of the venous network of each muscle facilitates the pumping of blood through the blood vessels in the venous network as the muscle contracts and relaxes. Typically, when the muscles of, for example, the calf of the leg are in a relaxed state, the adjacent blood vessels are in an expanded state, and on contraction of the calf muscles the blood vessels are squeezed between the muscles, thus causing blood to flow from the blood vessels. The valving system at the inlet to and the outlet from each blood vessel is arranged so that muscle pump assisted blood flow is directed back to the heart.

Poor blood circulation in the leg, in general, is exacerbated if the subject spends large amounts of time in a standing position. Due to the stationary nature of the subject, the calf muscle pumps are inactive, and as a result the extra assistance which could otherwise be obtained from the calf muscle pumps is unavailable.

There is therefore a need for an apparatus for improving muscle pump assisted blood flow in a subject, and in particular, in a limb of a subject. There is also a need for a method for improving muscle pump assisted blood flow in a subject.

- 5 The present invention is directed towards providing such an apparatus and a method.

According to the invention there is provided apparatus for improving muscle pump assisted blood flow in a limb of a subject, the apparatus comprising a first monitoring
10 means for monitoring muscle pump activity in the limb of the subject and for outputting a signal indicative of the level of muscle pump activity in the limb, a stimulating means for attaching to the limb of the subject for stimulating muscle pump activity in the limb, and a control means for reading the signal from the first monitoring means and for activating the stimulating means for stimulating muscle
15 pump activity in the limb in response to the signal received from the first monitoring means indicating an inadequate level of muscle pump activity.

Preferably, the control means comprises a storing means for storing a reference threshold value of muscle pump activity level, and a comparing means for comparing
20 the monitored muscle pump activity level indicated by the signal from the first monitoring means with the reference threshold value, the control means being responsive to the comparing means determining that the monitored muscle pump activity level is less than the reference threshold value for activating the stimulating means.

25 In one embodiment of the invention the stimulating means is selectively operable at a plurality of stimulating levels.

In another embodiment of the invention the control means is responsive to the
30 comparing means determining that the monitored muscle pump activity level is less than the reference threshold value for activating the stimulating means at one level greater than the level at which the stimulating means was last activated, subject to a maximum stimulation level.

In a further embodiment of the invention the control means is responsive to the comparing means determining that the monitored muscle pump activity level is greater than the reference threshold value for activating the stimulating means at one level less than the level at which the stimulating means was last activated,
5 subject to a minimum stimulation level.

In a still further embodiment of the invention the control means is responsive to the comparing means determining that the monitored muscle pump activity level is equal
10 to the reference threshold value for activating the stimulating means at a level similar to the level at which the stimulating means was last activated.

In one embodiment of the invention the control means reads the signal from the first monitoring means for a predetermined monitoring period of time, and the control means comprises a computing means for computing the average muscle pump
15 activity level during the predetermined monitoring period of time.

In one embodiment of the invention the predetermined monitoring period of time lies in the range of one minute to fifteen minutes. Preferably, the predetermined monitoring period of time lies in the range of three minutes to ten minutes.
20 Advantageously, the predetermined monitoring period of time is five minutes, approximately.

In another embodiment of the invention the reference threshold value stored in the storing means is a reference threshold value of average muscle pump activity, and
25 the comparing means compares the computed average muscle pump activity with the reference threshold value.

Ideally, the control means operates the apparatus through sequential cycles each of predetermined cycle duration, and preferably, the control means activates the
30 stimulating means during each cycle in which the stimulating means is to be activated in response to the monitored muscle pump activity level monitored in the previous cycle.

In one embodiment of the invention each cycle duration lies in the range of one minute to fifteen minutes. Preferably, each cycle duration lies in the range of three minutes to ten minutes. Advantageously, each cycle duration is five minutes, approximately.

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Ideally, the control means activates the stimulating means at the end of each cycle.

In one embodiment of the invention the predetermined monitoring period of time is at least 50% of each cycle duration. Preferably, the predetermined monitoring period of time is at least 75% of each cycle duration. Advantageously, the predetermined monitoring period of time is just less than each cycle duration.

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In one embodiment of the invention a second monitoring means is provided for monitoring the arterial pulse of the subject and for outputting a signal indicative of the arterial pulse, the control means being responsive to the second monitoring means for activating the stimulating means in synchronisation with the arterial pulse so that the stimulation of the muscle pump activity by the stimulating means combines with the arterial pulse for assisting blood flow in the limb of the subject. Preferably, the second monitoring means is adapted for mounting on a wrist or neck of the subject for detecting a wrist or neck pulse.

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In one embodiment of the invention the first monitoring means comprises an electrogoniometer for detecting movement in a joint of the limb of the subject for indirectly detecting muscle pump activity. Suitably, the electrogoniometer is adapted for attaching to a knee joint of the subject. Alternatively, the electrogoniometer is adapted for attaching to an ankle joint of the subject.

25

In another embodiment of the invention the electrogoniometer is adapted for attaching to an elbow joint of the subject, and in an alternative embodiment of the invention the electrogoniometer is adapted for attaching to a wrist joint of the subject. In a further alternatively embodiment of the invention the electrogoniometer is adapted for attaching to a shoulder joint of the subject.

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In an alternative embodiment of the invention the first monitoring means is an accelerometer. Preferably, the accelerometer is adapted for mounting on a leg of the subject. Advantageously, the accelerometer is adapted for attaching to a leg of the subject adjacent the calf of the leg. Alternatively, the accelerometer is adapted for mounting on a foot of the subject.

In a further alternative embodiment of the invention the accelerometer is adapted for mounting on an arm of the subject.

10 In a still further alternative embodiment of the invention the first monitoring means comprises an electromyograph comprising at least two electrodes adapted for attaching to the skin of the limb of the subject at spaced apart locations adjacent the muscle, the muscle pump activity level of which is to be determined.

15 In another alternative embodiment of the invention the first monitoring means comprises a blood flow monitoring means for attaching to the limb of the subject for measuring the velocity of blood flow. Preferably, the blood flow monitoring means is adapted for monitoring blood flow through the muscle, the muscle pump activity level of which is to be monitored. Advantageously, the blood flow monitoring means
20 comprises a Doppler flow probe.

In a still further alternative embodiment of the invention the first monitoring means comprises a blood pressure sensor for measuring the venous blood pressure in the limb.

25

In one embodiment of the invention the stimulating means comprises an electrical muscle stimulator for applying a voltage to the muscle, the muscle pump activity of which is to be stimulated.

30 In another embodiment of the invention the stimulating means comprises a chemical dispensing means for dispensing a muscle pump activity stimulating chemical or drug, and preferably, the chemical dispensing means is adapted for dispensing the chemical or drug into the muscle, the muscle pump activity of which is to be stimulated.

Alternatively, the stimulating means comprises a mechanical stimulating means for attaching to the limb of the subject, and preferably, the mechanical stimulating means is adapted for massaging the skin of the subject adjacent the muscle, the muscle pump activity of which is to be stimulated.

Advantageously, the mechanical stimulating means comprises an inflatable stocking or band for placing around the limb of the subject, and the control means comprises a means for controlling the inflation of the stocking or band for alternately squeezing and expanding the muscle.

In one embodiment of the invention a first mounting means is provided for mounting the stimulating means on the limb of the subject, and preferably, a second mounting means is provided for mounting the first monitoring means to the limb of the subject.

In one embodiment of the invention a housing is provided for housing the control means. Preferably, the housing is a portable housing, and is adapted for mounting on the subject. Advantageously, the housing is adapted for mounting on the trunk of a subject, and ideally, the housing is adapted for mounting on a waistband or belt worn by the subject.

In a further embodiment of the invention a power supply means is provided for powering the apparatus, and preferably, the power supply means is located in the housing so that the apparatus is portable and is suitable for use by an ambulatory patient.

Additionally, the invention provides a method for improving muscle pump assisted blood flow in a limb of a subject, the method comprising the steps of monitoring muscle pump activity in the limb of the subject, and stimulating muscle pump activity in the limb in the event that the monitored level of muscle pump activity is inadequate.

In one embodiment of the invention the muscle pump activity in the limb is monitored directly. Alternatively, the muscle pump activity in the limb is monitored indirectly.

In one embodiment of the invention the stimulating of the muscle pump activity is carried out by electrical stimulation. Alternatively, the stimulating of the muscle pump activity is carried out by mechanical stimulation.

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In a further alternative embodiment of the invention the stimulating of the muscle pump activity is carried out by chemical or drug stimulation.

10 In one embodiment of the invention the muscle pump activity is monitored by an electrogoniometer attached to the limb of the subject. Preferably, the muscle pump activity is monitored by an electrogoniometer attached to a joint of the limb of the subject.

15 In an alternative embodiment of the invention the muscle pump activity is monitored by electromyography, electrodes of an electromyograph being attached to the skin of the limb of the subject at spaced apart locations adjacent the muscle, the muscle pump activity of which is to be monitored.

20 In a still further alternative embodiment of the invention the muscle pump activity is monitored by an accelerometer attached to the limb of the subject.

Alternatively, the muscle pump activity is monitored by monitoring blood flow in the limb of the subject.

25 In a further alternative embodiment of the invention the muscle pump activity is monitored by monitoring venous blood pressure in the limb of the subject.

30 Preferably, the muscle pump activity is monitored for a predetermined monitoring period of time, and average muscle pump activity being determined over the monitoring period, and advantageously, the monitored muscle pump activity is compared with a reference threshold value. Ideally, the muscle pump activity is stimulated if the monitored muscle pump activity level is less than the reference threshold value.

In another embodiment of the invention the muscle pump activity may be stimulated at a plurality of stimulating levels, and on the monitored muscle pump activity level being less than the reference threshold value the muscle pump activity is stimulated at a level one level greater than the last level at which the muscle pump activity was stimulated, subject to a maximum level of stimulation.

Advantageously, on the monitored muscle pump activity being greater than the reference threshold value the muscle pump activity is stimulated at a level one level less than the last level at which the muscle pump activity was stimulated, subject to a minimum level of stimulation. Preferably, the muscle pump activity is stimulated at a level similar to the level at which it was last stimulated on the monitored muscle pump activity being equal to the reference threshold value.

Ideally, the muscle pump activity is monitored in sequential cycles, and the muscle pump activity is stimulated in each cycle in which muscle pump activity is to be stimulated in response to the muscle pump activity monitored in the previous cycle.

The invention will be more clearly understood from the following description of some preferred embodiments thereof which are given by way of example only with reference to the accompanying drawings, in which:

Fig. 1 is a schematic block representation of apparatus according to the invention for improving muscle pump activity in the limb of a subject,

Fig. 2 is a more detailed block representation of apparatus according to another embodiment of the invention for improving muscle pump activity in the limb of the subject,

Fig. 3 illustrates a flowchart of a program for controlling the apparatus of Fig. 2 to operate in one implementation, and

Fig. 4 illustrates a flowchart of a program for controlling the operation of the apparatus of Fig. 2 operating in another implementation.

Referring to the drawings and initially to Fig. 1, there is illustrated in broad outline apparatus according to the invention which is indicated generally by the reference numeral 1 for improving muscle pump assisted blood flow in a limb of a human subject, in this case, for improving muscle pump assisted blood flow in the calf muscles 2 of a lower leg 3 or legs 3 of the subject. The apparatus 1 comprises a control means, in this embodiment of the invention a closed loop controller 5 for controlling the apparatus 1. A first monitoring means provided by a sensor 7 which will be described in more detail below is adapted for attaching to the leg 3 of the subject for monitoring muscle pump activity in the calf muscle 2, either directly or indirectly. A stimulating means for stimulating muscle pump activity in the calf muscle 2 of the subject comprises an actuator 8 which will also be described in more detail below. The actuator 8 is adapted for attaching to the leg 3 of the subject adjacent the calf muscle 2, the muscle pump assisted blood flow of which is to be improved. The actuator 8 is operated under the control of the controller 5 in response to the muscle pump activity monitored by the sensor 7, and is activated for stimulating muscle pump activity on the monitored muscle pump activity being determined as being inadequate. Output signals from the sensor 7 which are indicative of the muscle pump activity of the muscle are fed to an averaging circuit 6 which reads and sums the signals received from the sensor 7 over a predetermined monitoring period of time and computes the average level of muscle pump activity over the predetermined monitoring period, which typically is just less than five minutes. The average level of muscle pump activity is fed to a comparator 9 which compares the average level from the averaging circuit 6 with a stored reference threshold value from a storing means, namely, a random access memory (RAM) 10. The reference threshold value corresponds to a reference threshold value of desired average muscle pump activity. The output from the comparator 9 is read by the controller 5, and on the comparator output indicating that the average monitored level of muscle pump activity is less than the reference threshold value the controller 5 operates the actuator 8 for stimulating the calf muscle pump activity.

A second monitoring means, namely, an arterial pulse monitor 12 is provided for monitoring the arterial pulse of the subject. The arterial pulse monitor 12 is suitable for attaching to the wrist or neck of the subject for monitoring the wrist or neck pulse. The controller 5 reads the pulse monitor 12 for determining the arterial pulse 12 and

activates the actuator 8 in synchronisation with the pulse of the subject so that the resultant muscle pump assisted blood flow caused by muscle pump activity co-operates with the arterial pump for assisting blood flow through the leg of the subject. A battery powered power supply circuit 14 powers the controller 5 and the
5 apparatus 1 so that the apparatus is portable and can be used and worn by an ambulatory subject.

A relatively small portable housing (not shown) is provided for housing the parts of the apparatus which are not to be attached to the leg 3 or wrist or neck of the
10 subject, and the housing (not shown) is adapted to be worn by the subject about the trunk of the subject, for example, the housing is typically adapted for attaching to a waistband, or waist belt worn by the subject. The housing (not shown) typically houses the controller 5, the averaging circuit 6, the comparator 9, the RAM 10 and the power supply circuit 14.

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The actuator 8 may be any suitable actuator, for example, the actuator may stimulate muscle pump activity by electrical, mechanical or chemical stimulation. A suitable electrical stimulator is a functional electrical stimulator which outputs a voltage pulse for passing through the calf muscle 2. A pair of electrodes (not shown)
20 are provided for attaching to the surface of the skin of the subject at spaced apart locations adjacent the calf muscle for applying the voltage to the calf muscle for stimulation thereof. The electronic circuitry of the functional electrical stimulator would be mounted in the housing (not shown), and a first mounting means provided by a suitable leg band (not shown) would be provided for securing the electrodes
25 (not shown) at appropriate spaced apart locations to the leg 3 adjacent the calf muscle 2.

Alternatively, the actuator 8 may be provided by a mechanical stimulator, such a stimulator may be provided by an inflatable stocking or leg band which would extend
30 substantially the length of the calf muscle 2. An inflating means, for example, an air pump would be located in the housing for inflating the stocking or leg band under the control of the controller 2. The band or stocking would be of the type which can be sequentially inflated from top to bottom or from bottom to top for sequentially squeezing and relaxing the muscle from top to bottom or vice versa for stimulating

muscle pump activity. Alternatively, the inflatable stocking or leg band may be alternately inflated and deflated for simply alternatively squeezing and relaxing the muscle, likewise for stimulating muscle pump activity. Appropriate valving would also be provided in conjunction with the air pump for appropriately inflating and deflating
5 the inflatable stocking or band. Indeed, instead of an air pump, a canister of pressurised gas may be provided. The air pump or other suitable inflating means and the valving would be housed in the housing (not shown).

The actuator 8 may be provided by a chemical or a drug stimulator. In which case
10 the actuator may be provided by a patch containing a suitable chemical or drug for stimulating muscle pump activity. The first mounting means would, typically, be a band which would be provided for securing the patch to the leg 3 adjacent the calf muscle 2. On being activated the patch would deliver an appropriate quantity of the chemical or drug to the skin of the subject for absorption therethrough to the calf
15 muscle. In this embodiment of the invention the patch could be activated for delivering the chemical or drug in response to a signal directly from the controller 5.

The sensor 7 may be provided by any suitable sensor, for example, an electrogoniometer of the type which detects movement of a joint and outputs and
20 electrical signal which is proportion to the movement or amount of movement of the joint, or is indicative of the amount of joint activity. A second mounting means, for example, a band would be provided for mounting the electrogoniometer to the joint in the leg of the subject, which, may be a knee joint or an ankle joint. By attaching the electrogoniometer to an ankle joint, the plantarflexion initiated by the calf muscle
25 may be detected. Thus, an electrogoniometer is particularly suitable for indirectly monitoring muscle pump activity in the calf muscle. Alternatively, the sensor 7 may be provided by an accelerometer attached at a suitable site, typically on the lower leg, and preferably, adjacent the calf muscle, although, the accelerometer may be attached to the foot. A suitable band would be provided for attaching the
30 accelerometer to the leg or foot of the subject. The accelerometer provides an output signal, typically, an output voltage which is proportional to the acceleration of the part of the limb to which the accelerometer is attached, thereby giving an indirect measurement of muscle pump activity in the calf muscle 2. A further alternative sensor 7 is an electromyograph which directly monitors muscle pump activity. The

electromyograph is provided with a pair of electrodes which are attached at spaced apart locations by a suitable band to the surface of the skin of the leg 3 adjacent the calf muscle 2. The muscle activity of the calf muscle 2 generates a voltage across the electrodes (not shown) of the electromyograph (also not shown) which is
5 proportional to the level of muscle activity, and in turn, is proportional to the muscle pump activity of the calf muscle 2. Suitable circuitry of the electromyograph which would be housed in the housing (not shown) analyses the voltage signals from the electrodes and outputs a signal to the averaging circuit 6 which is indicative of the level of muscle pump activity in the calf muscle 2.

10

Alternatively, the sensor 7 may be provided by a blood flow monitoring means, namely, a Doppler flow probe which would be attached by a suitable band to the surface of the skin of the leg 3 of the subject adjacent the calf muscle 2. The Doppler probe would output a signal which would be proportional to the Doppler shifted
15 signal, the shift magnitude of which is proportional to the velocity of blood flow inside a blood vessel adjacent the Doppler flow probe. By determining the velocity of blood flow a measure of the muscle pump activity is determined. Electrical circuitry (not shown) which would be housed in the housing (not shown) would analyse the signal from the Doppler flow probe, and would output a signal to the averaging circuit 6
20 indicative of the muscle pump activity.

A further alternative actuator 7 may be provided by a blood pressure monitoring means, namely, a blood pressure sensor which would monitor blood pressure at a suitable site on the leg of the subject, adjacent the ankle. The blood pressure
25 monitored would be inversely proportional to muscle pump activity. It is known that blood pressure adjacent the ankle increases as muscle pump activity decreases. Any suitable blood pressure sensor may be used and signals derived from the sensor would be fed to suitable analysing circuitry (not shown) located in the housing (not shown), which would in turn output a signal indicative of muscle pump activity to
30 the averaging circuit 6. The above described sensors 7 and actuators 8 would allow monitoring and stimulation of muscle pump activity without imposing any limitations on the ambulatory or any other state of the subject. In other words, the subject can be in any desired state, ambulatory or otherwise during monitoring and stimulation of the muscle pump activity.

In use, the apparatus 1 sequentially cycles continuously from one cycle to the next. In this embodiment of the invention each cycle is of duration of approximately five minutes. The averaging circuit 6 continuously reads the sensor 7 for monitoring muscle pump activity during the cycle and just before the end of each cycle

5 averages the muscle pump activity during the cycle. The average value of muscle pump activity is fed to the comparator 9 where the average monitored level of muscle pump activity is compared with the reference threshold value. The controller

10 5 determines from the output value of the comparator 9 if the average monitored muscle pump activity is less than the reference threshold value, and if so the controller 5 activates the actuator 8 at the end of the next cycle for stimulating the muscle pump activity in the calf muscle 2. When activating the actuator 8 to stimulate muscle pump activity in the calf muscle 2 the controller 5 activates the actuator 8 in synchronisation with the arterial pump of the subject determined from the pulse monitor 12. In the event that the controller 5 determines from the signal

15 from the comparator 9 that the monitored average muscle pump activity is equal to or greater than the reference threshold value, the controller 5 leaves the actuator 8 inactive for the whole of the next cycle. The time period during which the actuator 8 is operated during a cycle in which it is to be operated will depend on the type of the actuator 8. In the event of the actuator 8 being provided by an actuator which

20 provides chemical stimulation the actuator 8 would be activated for a sufficient period of time to allow an appropriate predetermined quantity of the chemical or drug to be delivered to the skin of the subject. In the case of the actuator 8 being provided by a functional electrical stimulator, it is envisaged that the actuator 8 would provide one relatively short voltage pulse at a predetermined voltage level for a

25 predetermined time period once at the end of the cycle in which the actuator 8 is to be activated. Where the actuator 8 is provided by a mechanical stimulator, for example, an inflatable stocking or band, it is envisaged that the stocking or band would be activated for a period of time sufficient to give an adequate amount of muscle pump activity stimulation. Should the stimulation provided by the inflatable

30 stocking or band be relatively gentle, it is envisaged that in certain cases stimulation may continue during a substantial part of the cycle in which muscle pump activity stimulation is to be provided.

Referring now to Figs. 2 and 3 there is illustrated apparatus according to another embodiment of the invention which is indicated generally by the reference numeral 20 for improving muscle pump assisted blood flow in a limb of a subject, in this case, in a calf muscle 2 in the lower leg 3 of a subject, similar to the calf muscle 2 and lower leg 3 illustrated in Fig. 1. The apparatus 20 comprises a control circuit 21 having a controller 22, in this embodiment of the invention provided by a single chip controller of the type MC68HC11F1, which comprises an 8bit CPU, a 1024byte RAM and 512byte EEPROM, and operates at 4MHz Bus Clock. A first monitoring means comprises an accelerometer 23 which is secured to a leg band 24 for attaching to the leg 3 of the subject adjacent the calf muscle 2 for indirectly monitoring muscle pump activity of the calf muscle 2 by monitoring acceleration of the lower leg 3 of the subject. A second monitoring means comprising a pulse monitor 25 secured to a wrist band 26 is provided for attaching to the wrist of the subject for monitoring the arterial pulse. A stimulation means, in this embodiment of the invention a functional electrical stimulator which comprises an electrical pulse generating circuit 27 for generating a voltage pulse for outputting to a pair of electrodes 29. The electrodes 29 are located in the leg band 24 at spaced apart locations for engaging the skin of the leg 3 of the subject adjacent the calf muscle 2 for applying the voltage pulse to the calf muscle 2 for stimulating the calf muscle 2 for in turn stimulating muscle pump activity in the calf muscle 2. A driver circuit 30 operates the pulse generating circuit 27 under the control of the controller 22.

A battery powered power supply circuit 32 powers the controller 22 as well as the other components of the apparatus 20. An on/off switch 33 is provided for allowing the subject to switch the apparatus 20 on and off. A 32Kbyte read only memory (ROM) 34 stores a program which is described below for controlling operation of the apparatus 1. A 32Kbyte RAM 35 stores a reference threshold value of desired average muscle pump activity against which the average muscle pump activity monitored by the accelerometer 23 can be compared as will be described below. A light emitting diode 36 indicates to the subject the on/off status of the apparatus 20.

An amplifier 39, the gain of which is controlled by the controller 22 amplifies the output voltage signal from the accelerometer 23 which in turn is fed to a multi-plexer 40. An amplifier 41, the gain of which is also controlled by the controller 22 amplifies

the voltage output signal from the pulse sensor 25. The amplified signal from the amplifier 41 is fed to the multi-plexer 40, which under the control of the controller 22 alternately outputs the amplified signals from the accelerometer 23 and the pulse sensor 25 to a twelve bit analogue-to-digital converter, which is also controlled by the controller 22. The output from the analogue-to-digital converter 44 is read by the controller 22 under the control of the program stored in the ROM 34.

The apparatus 20 sequentially cycles from one cycle to the next. In this embodiment of the invention the duration of each cycle is approximately five minutes. The controller 22 continuously reads the output of the accelerometer 23 from the analogue-to-digital converter 44 for a monitoring period, which in this embodiment of the invention is just less than the five minutes cycle time. At the end of the monitoring period under the control of the program in the ROM 34 the controller 22 determines the average level of muscle pump activity monitored by the accelerometer 23. The controller 22 then compares the monitored average muscle pump activity with the threshold value in the RAM 18, and if the monitored average muscle pump activity is less than the threshold value a flag is set in the controller 22 for activating the pulse generating circuit 27 for applying a muscle stimulating voltage pulse to the electrodes 29 at the end of the next cycle. If the flag for activating the pulse generating circuit 27 is already set from the previous cycle the controller 22 operates the multi-plexer 40 for passing the output signal from the pulse sensor 25 to the analogue-to-digital converter 44, which is read by the controller 22 just prior to activating the pulse generating circuit 27 at the end of the cycle so that the pulse generating circuit 27 is activated in synchronisation with the arterial pump of the subject so that the resultant muscle pump assisted blood flow resulting from the muscle pump activity co-operates with the arterial pump for assisting venous blood flow through the leg back to the heart.

In the event that the controller 22 determines that the monitored average muscle pump activity is equal to or greater than the threshold value no action is taken by the controller 22 on the next cycle to activate the pulse generating circuit 27, and in that cycle the controller 22 only monitors the muscle pump activity by reading the output from the accelerometer 23 through the analogue-to-digital converter 44.

An input terminal 45 is provided to the controller 22 for facilitating connecting the controller 22 to a personal computer (not shown) for setting parameters of the apparatus 20 by a medical practitioner. The reference threshold value which is stored in the RAM 35 of the desired average muscle pump activity, the voltage level
5 of the stimulating pulse to be generated by the pulse generating circuit 27, and the duration of the pulse, as well as the number of pulses to be generated during each cycle in which the calf muscle is to be stimulated are inputted through the personal computer and stored in the RAM 10. In general, only one pulse is generated per cycle in which stimulation is required.

10

In this embodiment of the invention, all the components with the exception of the electrodes 29, the accelerometer 23 and pulse sensor 25 are housed within a housing which is illustrated by the broken lines 46. The housing 46 is a relatively small housing which is suitable for attaching to a waistband or belt worn by the
15 subject so that the apparatus 1 is entirely portable and can be worn and used by the subject in an ambulatory or any other state.

Turning now to Fig. 3 a flowchart illustrating the operation of the program in the ROM 34 for controlling operation of the apparatus 20 will now be described. Block 50
20 commences the first cycle, and the program moves to block 51 which reads the output signal from the accelerometer 23 for the monitoring period. The program then moves to block 52 which computes the average muscle pump activity monitored by the accelerometer 23 during the monitoring period. The program then moves to block 53 which reads the reference threshold value from the RAM 35 and moves the
25 program to block 54. Block 54 compares the computed monitored average muscle pump activity with the threshold value. If the monitored average muscle pump activity is less than the threshold value the program moves to block 55 which sets a flag in the controller 22 for causing the controller 22 to activate the pulse generating circuit 27 at the end of the next cycle. The program then moves to block 56. If block
30 54 determines that the monitored average muscle pump activity is greater than or equal to the threshold value stored in the RAM 35 the program moves to block 56. Block 56 checks if a flag has been set in the controller 22 from the previous cycle, and if not, the program moves to block 57 which causes the program to wait for the end of the cycle, and then return to block 51. On the other hand, should block 56

determine that a flag has been set from the previous cycle the computer program moves to block 58 which causes the controller 22 to read the pulse sensor 25, and the program then moves to block 59. Block 59 activates the driver circuit 30 for in turn activating the pulse generating circuit 27 for outputting the voltage pulse to the electrodes 29 for stimulating muscle pump activity in synchronisation with the arterial pump of the subject. The program then moves to block 57, which as already described causes the program to wait for the end of the cycle, and then returns the program to block 51 to commence the next cycle.

Turning now to Fig. 4 there is illustrated a program which may be stored in the ROM 34 of the apparatus 20 for operating the apparatus 20 according to an alternative algrithirm. The program is somewhat similar to that described with reference to Fig. 3, and blocks which are similar to the blocks of the program of Fig. 3 are identified by the same reference numerals.

In this embodiment of the invention the pulse generating circuit 27 is operable by the driver 30 for outputting voltage pulses at different voltage levels for different durations, subject to a maximum voltage level and time duration and a minimum voltage level and time duration.

Block 50 again starts the first cycle of the apparatus 1, and the program operates in similar fashion as the program of Fig. 3 down to block 53. However, in this embodiment of the invention block 54 determines three states of the monitored average muscle pump activity relative to the threshold value stored in the RAM 35. Should block 54 determine that the monitored average muscle pump activity is equal to the threshold value the program moves to block 65 which sets a flag in the controller 22 to cause the controller 22 at the end of the next cycle to activate the pulse generating circuit 27 through the driver circuit 30 to output a pulse of voltage and duration similar to the voltage and duration of the last pulse to have been outputted by the circuit 27. The program then moves to block 66. Should block 54 determine that the monitored average muscle pump activity is less than the threshold value, the program moves to block 67 which sets a flag in the controller 22 to cause the pulse generating circuit 27 at the end of the next cycle to output a pulse of voltage and duration at one level greater than the voltage and duration of the last

pulse to have been outputted by the circuit 27. The program after block 67 moves to block 66. Should block 54 determine that the monitored average muscle pump activity is greater than the threshold value a flag is set in the controller 22 which causes the controller 22 at the end of the next cycle to activate the pulse generating circuit 27 to output a pulse at a voltage and duration one level less than the level of the voltage and duration of the last pulse to have been outputted by the circuit 27. After block 68 the program moves to block 66. Block 66 reads the output from the pulse sensor 25 and moves to block 69. Block 69 checks the type of flag which was set from the previous cycle. If the flag was set by block 65 in the previous cycle the computer program moves to block 70 which causes the controller 22 to operate the driver circuit 30 for in turn causing the pulse generating circuit 27 to output a pulse at a voltage level and duration similar to the voltage level and duration of the last pulse outputted by the pulse generating circuit 27. The computer program then moves to block 71 which causes the program to wait until the end of the cycle and then returns the program to block 51. Should block 69 determine that the flag set in the previous cycle was set by block 67 the program moves to block 72 which activates the pulse generating circuit 27 through the driver circuit 30 to output a voltage pulse at a voltage level and duration one level greater than the voltage level and duration of the last pulse outputted by the pulse generating circuit 27. The program then moves to block 71 which returns the program to block 51 at the end of the cycle. On the other hand, should block 69 determine that the flag set in the previous cycle was set by block 68 the program moves to block 73 which activates the pulse generating circuit 27 through the driver circuit 30 to output a pulse at a voltage level and duration one level less than the voltage and duration at which the last pulse was outputted by the pulse generating circuit 27. The program then moves to block 71 which causes the program to wait until the end of the cycle and return to block 51. Block 70, 72 and 73 when causing the pulse generating circuit 27 to output the voltage level at the appropriate level causes the pulse to be outputted in synchronisation with the arterial pump of the subject which is determined as a result of reading the pulse sensor 25 by block 66.

While the apparatus according to the invention has been described for monitoring and stimulating muscle pump activity in the calf muscle of one leg, it will of course be appreciated that the apparatus can be provided for monitoring and stimulating

muscle pump activity in the calf muscles of both legs. In which case, it is envisaged that separate monitoring means and stimulating means would be provided for the respective legs, although, the reading of the monitoring means and activating of the stimulating means would be controlled from a single controller housed in a single housing. Additionally, it will be appreciated that the apparatus may be provided for monitoring and stimulating muscle pump activity in any muscle in any limb or limbs, or in any other part of the body of a subject.

While the apparatus according to the invention has been described for improving muscle pump assisted blood flow in a limb of a human subject, it will be appreciated that the apparatus may also be used for improving muscle pump assisted blood flow in a limb of an animal subject.

It is envisaged that in certain cases it may be suitable to locate the accelerometer in the housing of the apparatus, and when the housing is worn on the body of the subject, signals from the accelerometer would be indicative of movement of the subject and thus would be indicative of muscle pump activity in, for example, the leg.

It is also envisaged that when the monitoring of muscle pump activity is being carried out by electromyography a blanking circuit would be provided in the control circuit for disabling the amplifier 39 during stimulation of the calf muscle, in order to avoid the muscle pump activity caused by the stimulation being monitored.

Claims

1. Apparatus for improving muscle pump assisted blood flow in a limb of a subject, characterised in that the apparatus (1,20) comprises a first monitoring means (7,23) for monitoring muscle pump activity in the limb of the subject and for
5 outputting a signal indicative of the level of muscle pump activity in the limb, a stimulating means (8,29) for attaching to the limb of the subject for stimulating muscle pump activity in the limb, and a control means (5,22) for reading the signal from the first monitoring means (7,23) and for activating the stimulating means (8,29) for stimulating muscle pump activity in the limb in response to the signal received
10 from the first monitoring means (7,23) indicating an inadequate level of muscle pump activity.
2. Apparatus as claimed in Claim 1 characterised in that the control means (5,22) comprises a storing means (10,35) for storing a reference threshold value of
15 muscle pump activity level, and a comparing means (9,22) for comparing the monitored muscle pump activity level indicated by the signal from the first monitoring means (7,23) with the reference threshold value, the control means (5,22) being responsive to the comparing means (9,22) determining that the monitored muscle pump activity level is less than the reference threshold value for activating the
20 stimulating means (8,29).
3. Apparatus as claimed in Claim 1 or 2 characterised in that the stimulating means (8,29) is selectively operable at a plurality of stimulating levels.
- 25 4. Apparatus as claimed in Claim 3 characterised in that the control means (5,22) is responsive to the comparing means (9,22) determining that the monitored muscle pump activity level is less than the reference threshold value for activating the stimulating means (8,29) at one level greater than the level at which the stimulating means (8,29) was last activated, subject to a maximum stimulation level.
30
5. Apparatus as claimed in Claim 3 or 4 characterised in that the control means (5,22) is responsive to the comparing means (9,22) determining that the monitored muscle pump activity level is greater than the reference threshold value for activating

the stimulating means (8,29) at one level less than the level at which the stimulating means (8,29) was last activated, subject to a minimum stimulation level.

6. Apparatus as claimed in any of Claims 3 to 5 characterised in that the control means (5,22) is responsive to the comparing means (9,22) determining that the monitored muscle pump activity level is equal to the reference threshold value for activating the stimulating means (8,29) at a level similar to the level at which the stimulating means (8,29) was last activated.
7. Apparatus as claimed in any preceding claim characterised in that the control means (5,22) reads the signal from the first monitoring means (7,23) for a predetermined monitoring period of time, and the control means (5,22) comprises a computing means (6,22) for computing the average muscle pump activity level during the predetermined monitoring period of time.
8. Apparatus as claimed in Claim 7 characterised in that the predetermined monitoring period of time lies in the range of one minute to fifteen minutes.
9. Apparatus as claimed in Claim 7 or 8 characterised in that the predetermined monitoring period of time lies in the range of three minutes to ten minutes.
10. Apparatus as claimed in any of Claims 7 to 9 characterised in that the predetermined monitoring period of time is five minutes, approximately.
11. Apparatus as claimed in any of Claims 7 to 10 characterised in that the reference threshold value stored in the storing means (10,35) is a reference threshold value of average muscle pump activity, and the comparing means (9,22) compares the computed average muscle pump activity with the reference threshold value.
12. Apparatus as claimed in any preceding claim characterised in that the control means (5,22) operates the apparatus through sequential cycles each of predetermined cycle duration.

13. Apparatus as claimed in Claim 12 characterised in that the control means (5,22) activates the stimulating means (8,29) during each cycle in which the stimulating means is to be activated in response to the monitored muscle pump activity level monitored in the previous cycle.
- 5
14. Apparatus as claimed in Claim 12 or 13 characterised in that each cycle duration lies in the range of one minute to fifteen minutes.
15. Apparatus as claimed in any of Claims 12 to 14 characterised in that each
10 cycle duration lies in the range of three minutes to ten minutes.
16. Apparatus as claimed in any of Claims 12 to 15 characterised in that each cycle duration is five minutes, approximately.
- 15
17. Apparatus as claimed in any of Claims 12 to 16 characterised in that the control means (5,22) activates the stimulating means (8,29) at the end of each cycle.
18. Apparatus as claimed in any of Claims 7 to 17 characterised in that the
predetermined monitoring period of time is at least 50% of each cycle duration.
20
19. Apparatus as claimed in any of Claims 7 to 18 characterised in that the predetermined monitoring period of time is at least 75% of each cycle duration.
20. Apparatus as claimed in any of Claims 7 to 19 characterised in that the
25 predetermined monitoring period of time is just less than each cycle duration.
21. Apparatus as claimed in any preceding claim characterised in that a second monitoring means (12,25) is provided for monitoring the arterial pulse of the subject and for outputting a signal indicative of the arterial pulse, the control means (5,22)
30 being responsive to the second monitoring means (12,25) for activating the stimulating means (8,29) in synchronisation with the arterial pulse so that the stimulation of the muscle pump activity by the stimulating means (8,29) combines with the arterial pulse for assisting blood flow in the limb of the subject.

22. Apparatus as claimed in Claim 21 characterised in that the second monitoring means (12,25) is adapted for mounting on a wrist or neck of the subject for detecting a wrist or neck pulse.

5 23. Apparatus as claimed in any preceding claim characterised in that the first monitoring means (7,23) comprises an electrogoniometer for detecting movement in a joint of the limb of the subject for indirectly detecting muscle pump activity.

24. Apparatus as claimed in Claim 23 characterised in that the electrogoniometer
10 is adapted for attaching to a knee joint of the subject.

25. Apparatus as claimed in Claim 23 characterised in that the electrogoniometer is adapted for attaching to an ankle joint of the subject.

15 26. Apparatus as claimed in Claim 23 characterised in that the electrogoniometer is adapted for attaching to an elbow joint of the subject.

27. Apparatus as claimed in Claim 23 characterised in that the electrogoniometer is adapted for attaching to a wrist joint of the subject.
20

28. Apparatus as claimed in Claim 23 characterised in that the electrogoniometer is adapted for attaching to a shoulder joint of the subject.

29. Apparatus as claimed in any preceding claim characterised in that the first
25 monitoring means (7,23) is an accelerometer.

30. Apparatus as claimed in Claim 29 characterised in that the accelerometer is adapted for mounting on a leg of the subject.

30 31. Apparatus as claimed in Claim 29 or 30 characterised in that the accelerometer is adapted for attaching to a leg of the subject adjacent the calf of the leg.

32. Apparatus as claimed in Claim 29 characterised in that the accelerometer is adapted for mounting on a foot of the subject.

33. Apparatus as claimed in Claim 29 characterised in that the accelerometer is
5 adapted for mounting on an arm of the subject.

34. Apparatus as claimed in any preceding claim characterised in that the first
monitoring means (7,29) comprises an electromyograph comprising at least two
electrodes adapted for attaching to the skin of the limb of the subject at spaced apart
10 locations adjacent the muscle, the muscle pump activity level of which is to be
determined.

35. Apparatus as claimed in any preceding claim characterised in that the first
monitoring means (7,23) comprises a blood flow monitoring means for attaching to
15 the limb of the subject for measuring the velocity of blood flow.

36. Apparatus as claimed in Claim 35 characterised in that the blood flow
monitoring means (7,23) is adapted for monitoring blood flow through the muscle,
the muscle pump activity level of which is to be monitored.

20

37. Apparatus as claimed in Claim 35 or 36 characterised in that the blood flow
monitoring means comprises a Doppler flow probe.

38. Apparatus as claimed in any preceding claim characterised in that the first
25 monitoring means (7,23) comprises a blood pressure sensor for measuring the
venous blood pressure in the limb.

39. Apparatus as claimed in any preceding claim characterised in that the
stimulating means (8,29) comprises an electrical muscle stimulator for applying a
30 voltage to the muscle, the muscle pump activity of which is to be stimulated.

40. Apparatus as claimed in any preceding claim characterised in that the
stimulating means (8,29) comprises a chemical dispensing means for dispensing a
muscle pump activity stimulating chemical or drug.

41. Apparatus as claimed in Claim 40 characterised in that the chemical dispensing means is adapted for dispensing the chemical or drug into the muscle, the muscle pump activity of which is to be stimulated.
- 5 42. Apparatus as claimed in any preceding claim characterised in that the stimulating means (8,29) comprises a mechanical stimulating means for attaching to the limb of the subject.
43. Apparatus as claimed in Claim 42 characterised in that the mechanical
10 stimulating means is adapted for massaging the skin of the subject adjacent the muscle, the muscle pump activity of which is to be stimulated.
44. Apparatus as claimed in Claim 42 or 43 characterised in that the mechanical stimulating means comprises an inflatable stocking or band for placing around the
15 limb of the subject, and the control means comprises a means for controlling the inflation of the stocking or band for alternately squeezing and expanding the muscle.
45. Apparatus as claimed in any preceding claim characterised in that a first mounting means (24) is provided for mounting the stimulating means on the limb of
20 the subject.
46. Apparatus as claimed in any preceding claim characterised in that a second mounting means (24) is provided for mounting the first monitoring means to the limb of the subject.
25
47. Apparatus as claimed in any preceding claim characterised in that a housing (46) is provided for housing the control means.
48. Apparatus as claimed in Claim 47 characterised in that the housing (46) is a
30 portable housing, and is adapted for mounting on the subject.
49. Apparatus as claimed in Claim 47 or 48 characterised in that the housing (46) is adapted for mounting on the trunk of a subject.

50. Apparatus as claimed in any of Claims 47 to 49 characterised in that the housing (46) is adapted for mounting on a waistband or belt worn by the subject.

51. Apparatus as claimed in any preceding claim characterised in that a power
5 supply means (14,32) is provided for powering the apparatus.

52. Apparatus as claimed in Claim 51 characterised in that the power supply means (14,32) is located in the housing (46) so that the apparatus is portable and is suitable for use by an ambulatory patient.

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53. A method for improving muscle pump assisted blood flow in a limb of a subject, the method comprising the steps of monitoring muscle pump activity in the limb of the subject, and stimulating muscle pump activity in the limb in the event that the monitored level of muscle pump activity is inadequate.

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54. A method as claimed in Claim 53 characterised in that the muscle pump activity in the limb is monitored directly.

55. A method as claimed in Claim 53 or 54 characterised in that the muscle
20 pump activity in the limb is monitored indirectly.

56. A method as claimed in any of Claims 53 to 55 characterised in that the stimulating of the muscle pump activity is carried out by electrical stimulation.

25 57. A method as claimed in any of Claims 53 to 56 characterised in that the stimulating of the muscle pump activity is carried out by mechanical stimulation.

58. A method as claimed in any of Claims 53 to 57 characterised in that the stimulating of the muscle pump activity is carried out by chemical or drug stimulation.

30

59. A method as claimed in any of Claims 53 to 58 characterised in that the muscle pump activity is monitored by an electrogoniometer attached to the limb of the subject.

60. A method as claimed in any of Claims 53 to 59 characterised in that the muscle pump activity is monitored by an electrogoniometer attached to a joint of the limb of the subject.

5 61. A method as claimed in any of Claims 53 to 60 characterised in that the muscle pump activity is monitored by electromyography, electrodes of an electromyograph being attached to the skin of the limb of the subject at spaced apart locations adjacent the muscle, the muscle pump activity of which is to be monitored.

10 62. A method as claimed in any of Claims 53 to 61 characterised in that the muscle pump activity is monitored by an accelerometer attached to the limb of the subject.

15 63. A method as claimed in any of Claims 53 to 62 characterised in that the muscle pump activity is monitored by monitoring blood flow in the limb of the subject.

20 64. A method as claimed in any of Claims 53 to 63 characterised in that the muscle pump activity is monitored by monitoring venous blood pressure in the limb of the subject.

65. A method as claimed in any of Claims 53 to 64 characterised in that the muscle pump activity is monitored for a predetermined monitoring period of time, and average muscle pump activity being determined over the monitoring period.

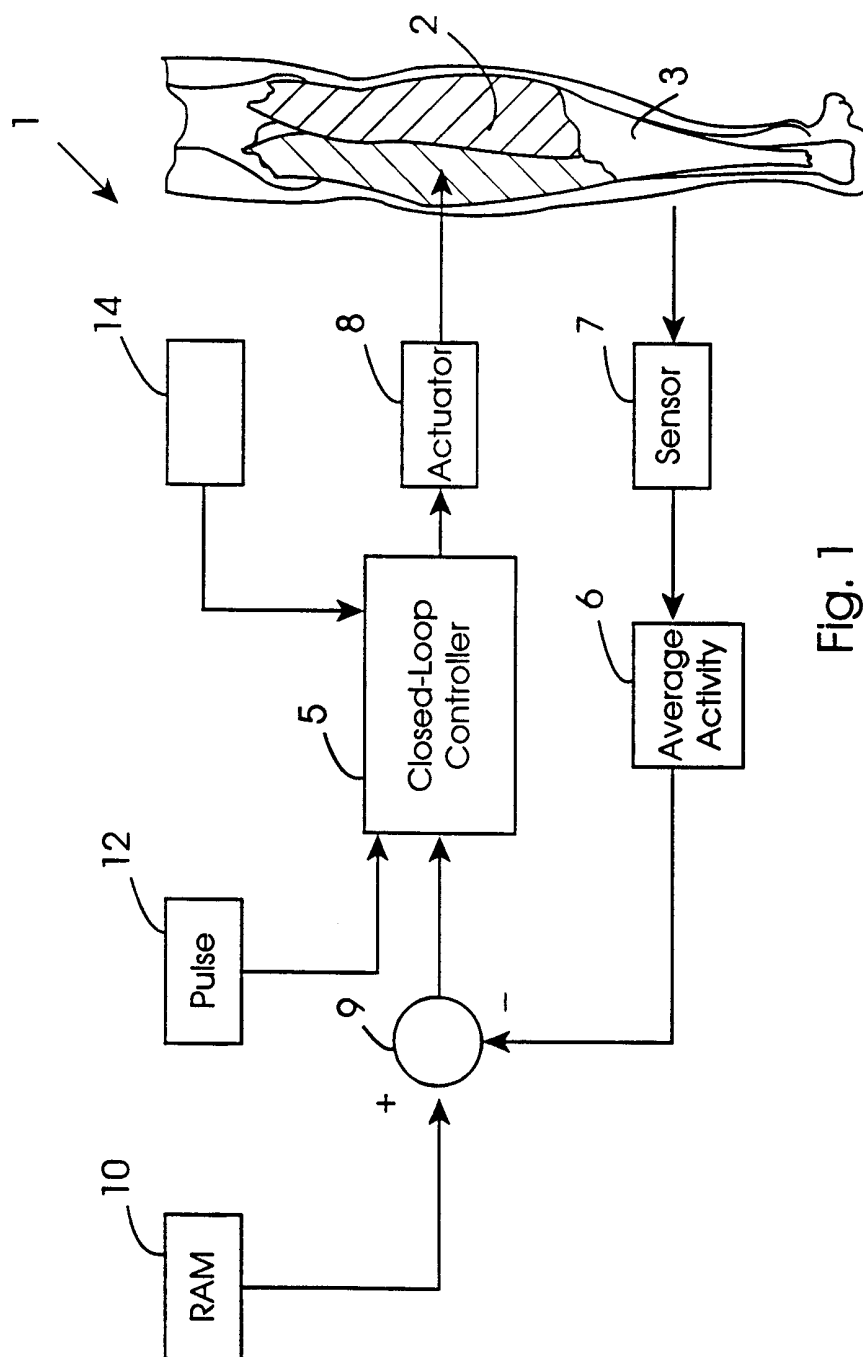
25 66. A method as claimed in any of Claims 53 to 65 characterised in that the monitored muscle pump activity is compared with a reference threshold value.

30 67. A method as claimed in Claim 66 characterised in that the muscle pump activity is stimulated if the monitored muscle pump activity level is less than the reference threshold value.

68. A method as claimed in Claim 66 or 67 characterised in that the muscle pump activity may be stimulated at a plurality of stimulating levels, and on the monitored muscle pump activity level being less than the reference threshold value

the muscle pump activity is stimulated at a level one level greater than the last level at which the muscle pump activity was stimulated, subject to a maximum level of stimulation.

- 5 69. A method as claimed in Claim 68 characterised in that on the monitored muscle pump activity being greater than the reference threshold value the muscle pump activity is stimulated at a level one level less than the last level at which the muscle pump activity was stimulated, subject to a minimum level of stimulation.
- 10 70. A method as claimed in Claim 68 or 69 characterised in that the muscle pump activity is stimulated at a level similar to the level at which it was last stimulated on the monitored muscle pump activity being equal to the reference threshold value.
- 15 71. A method as claimed in any of Claims 53 to 70 characterised in that the muscle pump activity is monitored in sequential cycles, and the muscle pump activity is stimulated in each cycle in which muscle pump activity is to be stimulated in response to the muscle pump activity monitored in the previous cycle.



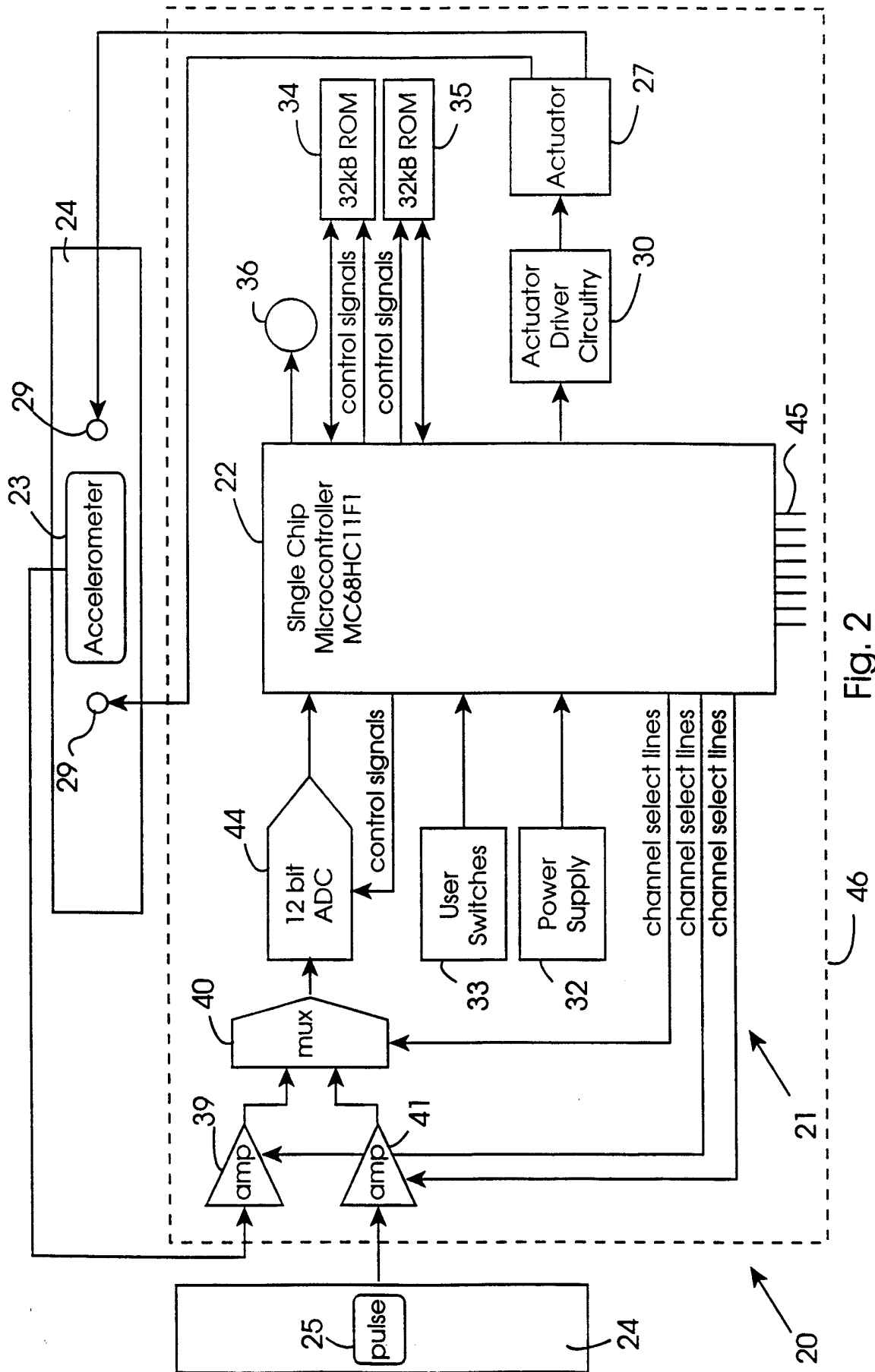
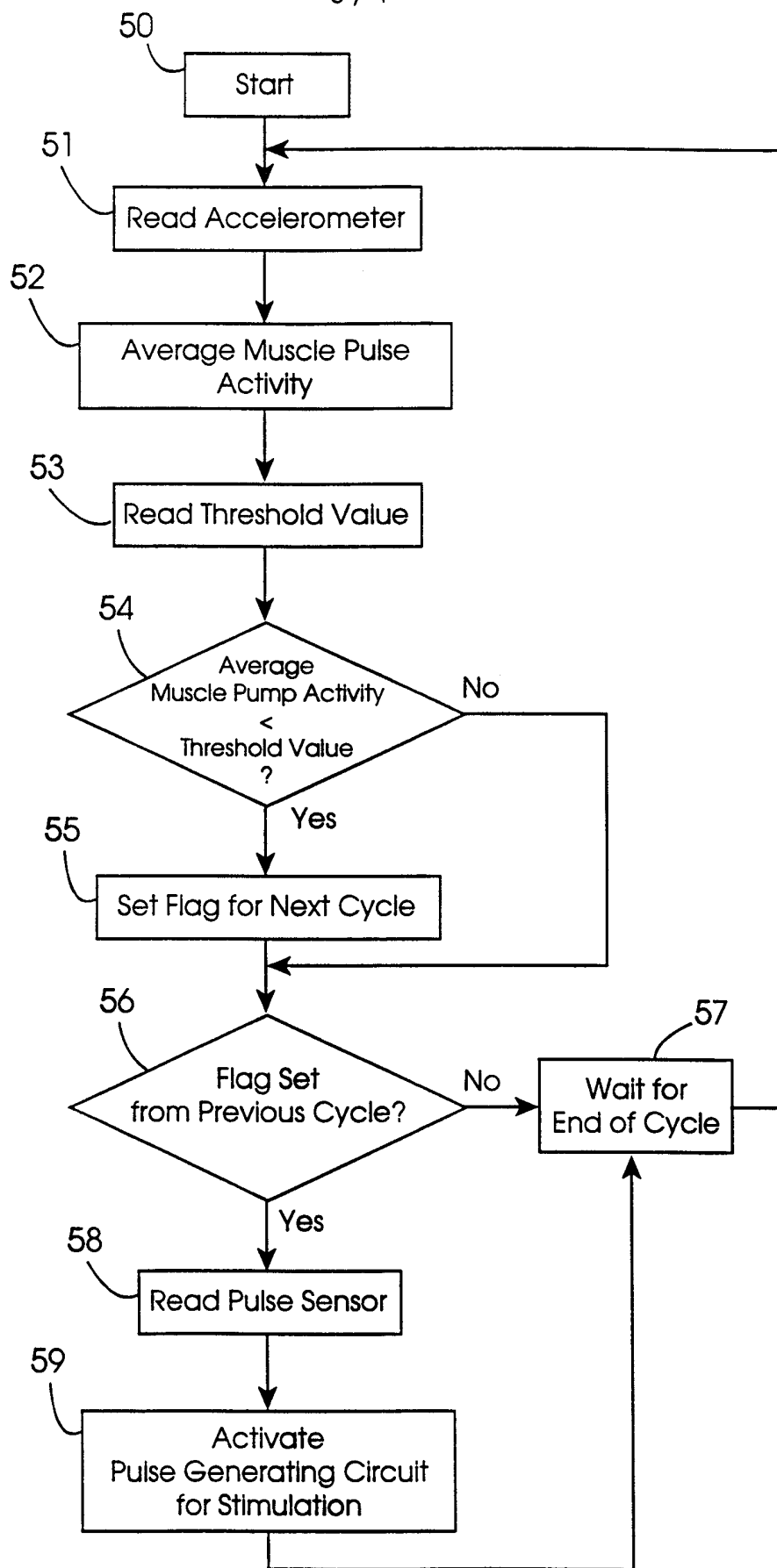
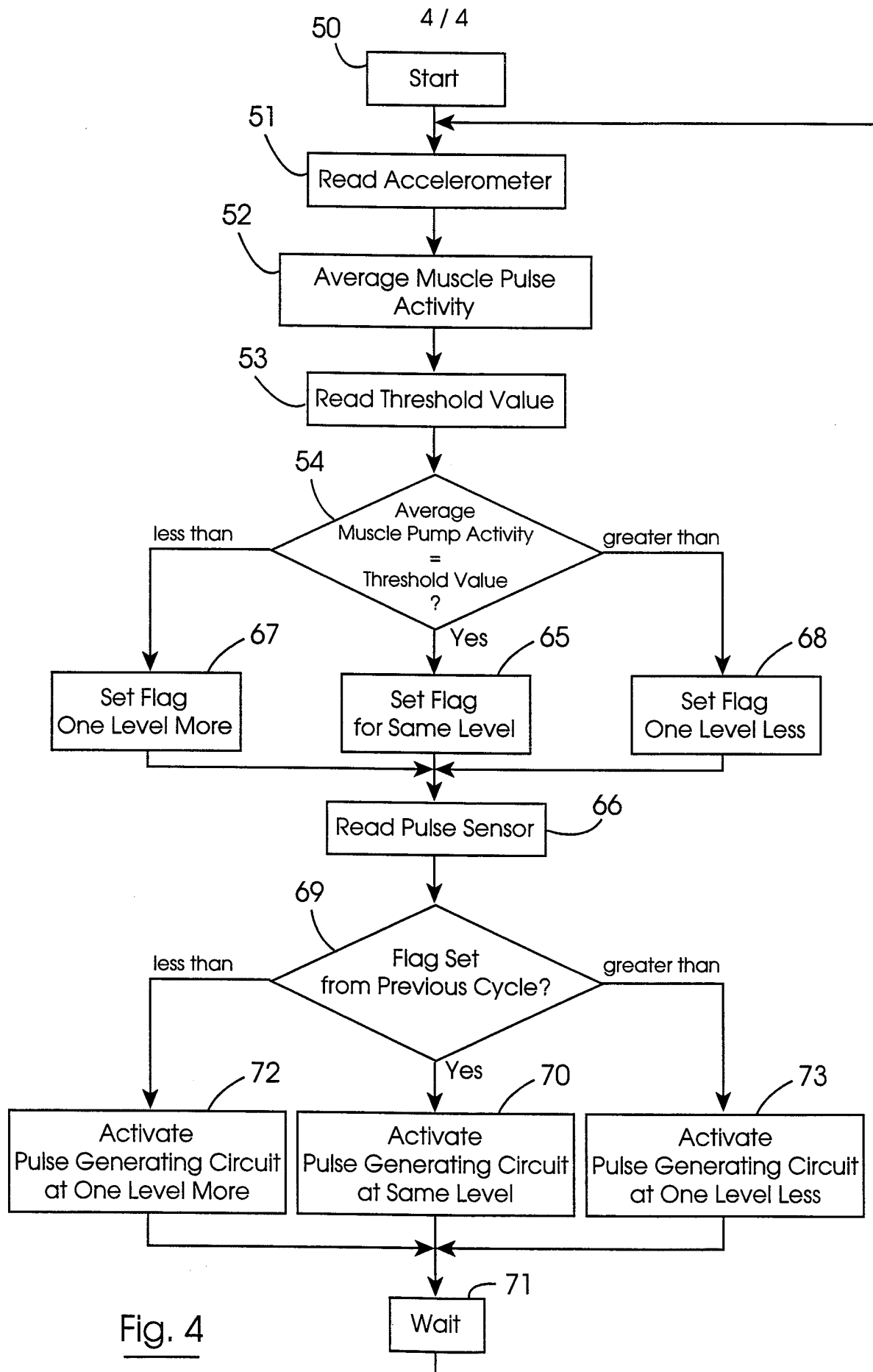


Fig. 2

Fig. 3



INTERNATIONAL SEARCH REPORT

International Application No

PC./IE 99/00079

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61H23/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61H

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 514 204 A (TUMEY ET AL.) 19 November 1992 (1992-11-19) page 2, line 1 - line 4 page 3, line 2 - line 20 page 3, line 50 - page 4, line 44 page 5, line 9 - line 17 figures 1,2 --- -/--	1-3, 35, 42-45, 47, 51

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

8 November 1999

Date of mailing of the international search report

12/11/1999

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INTERNATIONAL SEARCH REPORT

International Application No

PC/IE 99/00079

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 40806 A (WESTERN CLINICAL ENGINEERING LTD) 6 November 1997 (1997-11-06) page 11, line 20 -page 14, line 1 page 21, line 6 -page 23, line 4 page 25, line 26 - line 27 page 31, line 5 - line 30 page 33, line 23 - line 26 page 35, line 20 - line 27 figures 1,2,7,8,10 ---	1-7,11, 12,35, 37, 42-48, 51,52
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X	US 5 443 440 A (TUMEY ET AL.) 22 August 1995 (1995-08-22) column 1, line 65 -column 2, line 24 column 8, line 38 -column 9, line 68 figures 1,2,6 -----	1,7-9, 35,37, 42, 44-47,51

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IE 99/00079

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 53-71
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT-Method for treatment of the human or animal body by therapy
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

formation on patent family members

International Application No

PC, IE 99/00079

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