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Apparatus and Method for Enhanced HGH Generation in Humans

Field of the Invention

The present invention relates to a physical conditioning method for use with an exercise apparatus. In particular, the present invention relates to a conditioning method for enhancement of human growth hormone (HGH).

Background of the Invention

One prior art method of increasing muscle mass uses low-intensity resistance training where a relatively light and flexible cuff or elastic band is placed on the proximal part of a subject's lower or upper limbs, and the cuff or band provides sufficient constriction of the limb to reduce blood flow. The resultant reduction of blood flow generates blood pooling in the capillaries of the muscles opposite the blood flow constriction with relation to the

1 heart. The article "Effects of resistance exercise
2 combined with moderate vascular occlusion on muscular
3 function in humans" in J Appl Physiol 88: 2097-2106, 2000
4 by Takarada teaches muscle bulk enhancement by light
5 exercise in combination with vascular occlusion. One
6 exemplar system which provides this occlusion is the KAATSU
7 system of Sato, described in U.S. Patent application
8 2006/0281611 and Japan Patent application published as
9 PCT/JP2003/016163, and U.S. Patent application 7,413,527.
10 In this system, a constricting band is placed around a limb
11 that is being physically conditioned to increase lactic
12 acid buildup. Long term exertion which is at or below the
13 capillary blood oxygen replacement rate is known as aerobic
14 exercise, and short term exertion which is above muscle
15 capillary oxygen replacement rate is known as anaerobic
16 exercise. The prior art systems of Sato described above
17 relate to the combination of circulatory constriction and
18 aerobic exercise.

19
20 Objects of the Invention

21 A first object of this invention is a method for
22 enhancing HGH generation in a human subject, the method

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1 having a first step of application of pressurized cuffs to
2 subject extremities, the pressurized cuffs containing a
3 circulating fluid at a reduced temperature compared to the
4 temperature of human blood, the method having a second step
5 of providing a fluid flow and pressure at a range between
6 33% and 220% of systolic blood pressure, a third step of
7 subject ramp-up exertion for a duration of time until an
8 equilibrium is reached in heart rate and blood pressure, a
9 fourth step of repetitive intensive conditioning cycles,
10 each conditioning cycle having repetitive sequences of
11 intense high level exertion followed by low level exertion,
12 and a fifth step of application of a reduced temperature
13 flexible surface to a subject spine during a cooling down
14 interval.

15 A second object of the invention is a method for
16 enhanced oxygen transport to the brain following a vigorous
17 exercise interval by cooling CSF in the spinal column
18 through application of a flexible cooling pad to the spine
19 of a subject in a horizontal position, the flexible pad
20 having an elongate region carrying a circulated coolant
21 having a first temperature and surrounded by a second
22 region circulating a coolant having a higher temperature
23 than the coolant of the elongate region, the elongate

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1 region preferably providing coupling to a subject spinal
2 region.

3

4 Summary of the Invention

5 The present invention is a method for enhancement of
6 self-generated HGH in a human subject through the
7 application of pressure and cooling to the limbs of the
8 subject, in combination with physical exertion and
9 monitoring of heart rate and systolic blood pressure.
10 During a ramp-up interval, the subject engages in moderate
11 exertion until a steady state blood pressure and heart rate
12 is reached during the ramp-up phase, during which interval
13 limb cuff pressure set to a pressure P which is in the
14 range of 33% to 220% of systolic blood pressure. During
15 one or more subsequent conditioning cycles, each
16 conditioning cycle having a high rate of subject exertion
17 followed by a comparatively lower rate of subject exertion,
18 each conditioning cycle having an interval of intense
19 exertion in a range of duration of one to four minutes
20 followed by an interval of low exertion in a range of
21 duration of one to four minutes. Three such cycles are
22 provided, after which a cool-down cycle occurs. Following

1 the cool-down cycle, the subject is placed in a horizontal
2 position resting on a cooled spinal pad.

3 In another embodiment of the invention, a subject is
4 placed in a horizontal position on a cooling pad following
5 an interval of intense exercise, the cooling pad
6 preferentially removing heat from the spine and thereby
7 lowering the CSF temperature to improve delivery of CSF
8 oxygen to the brain.

9 In another embodiment of the invention, the subject
10 resting blood pressure is measured using pressure developed
11 in a pressurized cuff, and the resting blood pressure is
12 used in combination with a range such as 33% to 220% of
13 this resting blood pressure to provide a pressurized
14 cooling pressure which is later used during a pressurized
15 cooling phase.

16 In another embodiment of the invention, a subject in a
17 weightless environment with a series of pressurized cuffs,
18 the pressures and temperatures of the cuffs sequenced to
19 simulate walking or other exercise while in the weightless
20 environment, thereby improving circulation through the
21 veins.

1 In another embodiment of the invention, a subject in a
2 weightless environment wears inflatable cuffs, and periodic
3 pressures are to the cuffs in a sequence which provides for
4 closure of venous valves to prevent retrograde blood flow
5 and to improve circulation.

6
7
8 Brief Description of the Drawings

9 Figure 1 shows a diagram for a core cooling system.

10 Figure 1A shows a diagram of a subject extremity
11 enclosed by the pressure cooling system of figure 1.

12 Figures 2A and 2B show a diagram for a conditioning
13 process according to the present invention.

14 Figure 2C shows a spinal cooling process for use with
15 an exercise and conditioning process.

16 Figure 3 shows a plot of physical parameters of heart
17 rate and applied cuff pressure as measured in a subject
18 through the conditioning process.

19 Figure 4A shows pressure and cooling cuffs applied to
20 an astronaut in space.

1 Figures 4B, 4C, and 4D shows the response of a venous
2 artery and valve in a variety of different environmental
3 conditions.

4 Figure 4E shows a cross section view of a sequentially
5 inflating cuff.

6 Figure 5 shows a plot of applied cuff pressures over
7 time which provide for enhanced blood flow in a zero
8 gravity environment.

9 Figure 6 shows the diagram of a cooling mat in contact
10 with a user.

11 Figure 7 shows isoplanar temperature plot of the
12 cooling mat of figure 6.

13 Figure 7A shows the cross section view of the
14 temperature profile of figure 7.

15

16 Detailed Description of the Invention

17 Figure 1 shows a core cooling apparatus 100 for use
18 with the present conditioning process. A reservoir 104
19 provides a cooled heat transfer fluid 108 such as water
20 mixed with an anti-freeze such as ethylene glycol or anti-
21 bacterial or anti-fungal agent, the fluid 108 having a

1 temperature regulated by refrigeration/heat exchanger unit
2 112 which may include refrigeration coil 110 for removing
3 heat from fluid 108, with the refrigerator/heat exchanger
4 112 transferring removed heat energy to the external
5 environment. Circulated coolant 108 which leaves reservoir
6 104 is preferentially in the temperature range of (38 to 60
7 degrees Fahrenheit), and the coolant 108 is circulated from
8 pump 106 through a common manifold to pressure/cooling
9 cuffs 120, 122, 124, 126, 128, and 130, with pressures and
10 flows controlled by regulation valves 121, 123, 125, 127,
11 129, and 131 respectively. Each independently controlled
12 cuff provides pressure for reduction of blood circulation
13 and reduced temperature for suppression of the evaporative
14 cooling (sweating) response, with the fluid which leaves
15 the cuff thereafter draining back to reservoir 104 such as
16 through a return manifold 101. In particular, extremity
17 cuffs 122, 124, 128, and 130 are used to provide a
18 restriction in blood circulation in combination with
19 cooling of blood in the associated limbs.

20 The application of pressure to subject limbs at a
21 level sufficient to reduce circulation in combination with
22 the use of a refrigerated coolant for removal of heat

1 during physical exercise is referred to in the present
2 patent application as "core cooling" or "pressurized core
3 cooling". The applied cuff pressure P is typically a
4 fraction of systolic blood pressure at a level sufficient
5 to cause a "burning sensation" in subject muscles during
6 exertion (as determined by the comfort level of the
7 subject), but below the level of hypoxia or vascular
8 occlusion, and the preferred core cooling pressure varies
9 with systolic blood pressure, but is typically a fixed
10 fraction of the systolic blood pressure in the range 33% to
11 220% as described earlier. The measurement of blood
12 pressures may be incorporated into the blood pressure cuff
13 through the addition of a microphone sensor and the use of
14 the existing pressures developed in the cuff as part of the
15 pressurized cooling.

16 In another preferred embodiment of the invention, a
17 process for conditioning starts initially with reduced
18 mechanical resistance during initial exercise, after which
19 the level of exercise resistance (and associated exertion)
20 is increased. After an initial ramp-up interval, during
21 which blood pressure and heart rate reach equilibrium
22 values (and the operating pressure P may be adjusted based

1 on changes in physical parameters such as blood pressure),
2 a series of conditioning cycles are performed, the
3 conditioning cycles occurring in a group of one or more,
4 each conditioning cycle having intense subject physical
5 exertion lasting an interval of several minutes followed by
6 a reduced level workout for an interval of several minutes,
7 both the intense level and reduced level exertion being
8 done with a relatively constant limb pressure applied,
9 after which a rampdown interval occurs, followed by the
10 application of core cooling without pressure such as by
11 application of chilled coolant bladders to the spine and
12 back, with preferential cooling applied to the elongate
13 spinal region.

14 In one preferred embodiment of the invention, core
15 cooling is applied during the cooling-off interval
16 following exercise, which lowers the temperature of the
17 spine, resulting in lower cerebral spinal fluid (CSF)
18 temperature, and the reduced temperature CSF is capable of
19 supporting a greater partial pressure of dissolved oxygen.
20 The oxygen enhanced CSF is transported through the cooled
21 areas of the spine and to the four ventricles of the brain
22 such as by thermal convective circulation of the oxygen-

1 enhanced CSF, thereby enhancing the level of oxygen
2 provided to the brain.

3 The objective of core cooling is to optimize vascular
4 performance by slowing down venous blood flow during an
5 exercise interval lasting 20 minutes, or for a duration
6 sufficient to cause the pooling of lactic acid in muscle
7 tissue. Upon release of limb constriction after the
8 conditioning cycles, the rapid release of pooled lactic
9 acid provides stimulus to the subject's pituitary gland,
10 which triggers additional HGH production. Over a human
11 lifespan, HGH is produced by the body in comparatively high
12 levels during the pre-teenage years when the body is
13 functioning at a high metabolic rate compared to later
14 years. The human body loses approximately 14% of its HGH
15 production capability in each 10 year interval which
16 follows the peak production years surrounding puberty.
17 Measurements taken from healthy adults using the method and
18 apparatus of the present invention indicate that HGH levels
19 can be increased 300% above basal control levels through
20 the effect of pooling lactic acid in muscle tissue through
21 pressure cooling, which causes an enhanced pituitary gland
22 response, with subsequent increased HGH generation compared

1 to prior art systems. Recent measurements of HGH in
2 subjects using the present pressure cooling apparatus and
3 associated method of exercise indicate a 400% to 1200%
4 increase in HGH when performing aerobic exercise in the
5 core muscles and anaerobic exercise in the pressure-cooled
6 extremities. It is believed that the combination of
7 aerobic exercise with anaerobic pressure cooled extremities
8 is the best mode of the invention for optimal generation of
9 HGH.

10 The cooling method of the present apparatus and
11 related process provides specific benefit in increasing the
12 efficiency of HGH generation from vigorous exercise.
13 During typical exercise, electro-chemical reactions which
14 occur at the cellular level in the muscles cause heat
15 generation, and the mechanism used in humans to reduce heat
16 buildup is evaporative cooling at the skin surface which is
17 experienced as body sweat. The perspiration cooling
18 mechanism in humans results in blood being shunted from
19 providing nutrients and oxygen to muscle tissue and instead
20 the blood is used as a coolant to the skin instead of for
21 nutrient transport to the muscle groups in exertion. As
22 the subject exercises and core temperature rises, more

1 blood gets shunted from deep muscle tissue with nutrient
2 demand to the skin surface for body cooling. During
3 intense exercise, up to 40 percent of the blood flow is
4 shunted from exercising muscles to the skin surface for
5 body cooling, and the reduction in capillary flow through
6 the muscles is responsible for lactic acid burn experienced
7 during exercise. In the present invention, advantageous
8 pooling of lactic acid is provided by venous flow
9 restriction, and the pooling of lactic acid during the
10 ramp-up interval, and particularly during the conditioning
11 cycles, is suddenly released at the end of the last
12 conditioning cycle when the pressure cuffs are
13 depressurized or removed. This sudden release causes the
14 lactic acid to stimulate a pituitary gland response that is
15 larger than without pressure cooling of the present
16 invention because of the enhanced concentration of lactic
17 acid being released. The simultaneous application of
18 cooling with pressure keeps blood flow in the muscles,
19 rather than shunting blood flow to the skin surface,
20 resulting in maximum concentration of lactic acid and
21 maximum pituitary gland response. Chemical reactions in
22 the muscle tissue associated with muscle exertion also
23 causes warming of the blood, the elevated blood temperature

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1 results in a reduction of oxygen transport since the
2 elevated temperature causes a reduced hemoglobin
3 oxygenation capacity. In contrast, conductive and
4 convective surface cooling are experienced by a heavily
5 exerting swimmer who has greater circulation through muscle
6 and reduced loss of oxygen from elevated blood temperature.
7 The advantageous cooling provided by swimming is offset by
8 the disadvantage of the horizontal position during swimming
9 exertion, which reduces the effect of the venous valves
10 which provide protection against retrograde venous blood
11 flow. Additionally, during exertion with the body in a
12 vertical orientation, muscle forces related to the
13 particular foot and leg movements associated with
14 perambulation operate optimally on the venous blood valves
15 located throughout the muscles of the thighs and legs,
16 whereas the muscle groups associated with swimming and
17 kicking in the water do not work as efficiently as those of
18 walking on land. During exertion, the nearby muscle groups
19 are operating on the vein walls and valves. When in an
20 upright position, this results in a pumping action which
21 pushes blood back to the heart through the venous one way
22 valves which are located in muscle tissue, and the valve
23 and muscle pumping action is optimal when the circulatory

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1 system is operating in an upright vertical position. With
2 core cooling of the present invention, the reduction of
3 core body temperature combined with pressure cooling of the
4 extremities provides an increase in blood oxygen and a
5 reduction in the shunting of blood away from muscle tissue
6 as would be required for evaporative cooling from body
7 sweat.

8 In another aspect of the invention, grounding of the
9 body causes the release of serotonin responsible for deep
10 sleep. Serotonin release also contributes to the
11 generation of HGH. Grounding may be achieved by electrical
12 connection of the subject to a reference voltage referred
13 to as ground which is near to the subject, including a
14 metal enclosure or structure such as an exercise machine
15 operated by the subject, a surrounding enclosure such as a
16 space capsule used for space travel, or in terrestrial use,
17 the potential of earth which is adjacent to the subject.

18 In an aspect of the invention shown in figure 1A, the
19 pressure of each pressure cooling cuff 122, 124, 128, and
20 130 of figure 1 is individually set to an operational value
21 P which is selected from the range of 33% TO 220% of
22 systolic blood pressure, the operation of which is shown in

1 detail for a particular cuff 122 enclosing an extremity
2 160. In operation, a subject arm 160 with a typical vein
3 152 is subject to elevated pressure with cooling from inlet
4 176 which pressure is coupled to cuff 122 manifold 164,
5 passes through a plurality of flexible cuff passages 168
6 which expand and apply cooling and compressive pressure to
7 veins 152 in subject arm 160, with the coolant collected in
8 exit manifold 166 passing to regulation valve 123 and to
9 outlet 174. The pressure controller 170 increases the
10 pressure in the cuff 122 by reducing flow in valve 123
11 until systolic blood flow is no longer detected using
12 acoustic transducer 162 which is coupled to the subject's
13 arm 160. Pressure controller 170 takes a measurement of
14 pressure in the cuff 122 using pressure sensor 173 after
15 valve 123 flow is reduced to eliminate detected flow using
16 acoustic sensor 162. The operating pressure for
17 therapeutic purposes is then set to a fractional pressure P
18 such as 33% to 220% of this systolic pressure by increasing
19 flow in valve 123 until pressure detector 173 reports this
20 same desired operating pressure. The blood pressure
21 measurement process may be repeated at various intervals
22 during the exercise cycle since blood pressure may vary
23 during the course of the therapy. In a typical healthy

1 patient at rest, the systolic blood pressure may be 120 mm
2 Hg, whereas during the ramp-up phase of exercise, the
3 systolic blood pressure can reach 180 mm Hg, and a
4 conditioning cycle blood pressure may reach 190 mm Hg
5 resulting in an operational cuff pressure P of 96 mm Hg at
6 rest, and 144 mm Hg during ramp-up exercise. The cuff
7 pressure is tailored to each user based on the tradeoff
8 between optimizing HGH generation with increased pressure
9 and increased subject cooling versus optimizing patient
10 comfort associated with reduced pressure or reduced
11 cooling, which pressure and cooling parameters are also
12 affected by subject exercise exertion level during the
13 exercise and cool-down phases. In general, a wider cuff
14 provides an improved comfort level for the user which
15 translates into a longer exercise workout, as the
16 discomfort of constricting pressure on a narrow section of
17 a muscle group is reduced, and the addition of cooling in
18 the pressure cuff provides an extended and more effective
19 exercise interval by minimizing the HGH reduction caused
20 when blood is shunted from the muscles to the capillaries
21 at the skin surface and resulting in the generation of
22 sweat at the skin surface. It is believed that a liquid
23 pressurized and liquid cooled inflatable cuff which

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1 operates over the range of 20% to 80% of the length of the
2 muscle group provides for improved comfort. This provides
3 for a greatly improved duration of aerobic and anaerobic
4 exercise than would be available using cuff pressure alone.
5 Additionally, it is believed that the reduction in
6 temperature of the blood in the limbs enables greater
7 storage of oxygen in the blood, which enables extended
8 muscle exertion, which generates an increased level of
9 lactic acid, which triggers the generation of increased
10 levels of HGH by the pituitary gland.

11 Figure 2A shows a detailed view of the process 200
12 used in conjunction with the apparatus described in figures
13 1 and 1A. A subject at rest enters the exercise equipment
14 which is used in conjunction with pressure cooling in step
15 202, and has cooling pressure cuffs such as 120, 122, 124,
16 126, 128, 130 of figure 1 applied in step 204. Cuff
17 pressure is applied such as by enabling circulation pump
18 106 and closing valves 121, 123, 125, 127, 129, or 131 of
19 figure 1 in step 206, and during this interval, the
20 systolic blood pressure may be measured on a per-cuff
21 basis, or a single measurement made for application to all
22 cuffs. The blood pressure measurement can be made at any

1 time during the exercise regimen, preferably using the
2 method described for figure 1A. In step 208, the operating
3 cuff pressure is set to a threshold P derived from the
4 systolic blood pressure as previously described. In step
5 210 and 212, the subject ramps up to a strenuous level of
6 exercise and maintains this level for 20 minutes in step
7 212. During the ramp-up phase, the subject may adjust the
8 individual cuff pressures for comfort, or they may be
9 automatically re-computed as a fixed fraction of current
10 systolic blood pressure for a new operational pressure P
11 based on the systolic blood pressure measured as described
12 in figure 1A. An HGH pump conditioning cycle is shown in
13 steps 214, 216, 218, comprising strenuous exercise step 214
14 and reduced level of exercise 216, which is performed for a
15 number N of cycles 218, depending on protocol. Three
16 cycles (N=3) is a common conditioning cycle providing
17 satisfactory results. Upon completion of the protocol, a
18 cool down cycle occurs as shown in figure 2B comprising
19 depressurization of cuffs such as by turning off
20 circulation pump 106 or opening flow valves 121, 123, 125,
21 127, 129, and 131. The subject removes the depressurized
22 cuffs in step 242 and thereafter lies 244 on a cooling mat
23 for a cool down interval such as 20 minutes, where the

1 subject is in a horizontal position with the cooling mat
2 providing cooling to the spine, in particular to cool the
3 CSF as was described earlier with the patient in a
4 horizontal position. The interval of time spent in the
5 horizontal position on the cooling mat 244 is determined by
6 the amount of time required for the heart rate and blood
7 pressure to return to resting levels, as shown in figure 3.

8 Figure 2C shows the application of the beneficial CSF
9 cooling to any exercise regimen, with or without pressure
10 cooling of figure 1 and 1A. In this application, the
11 subject performs aerobic or anaerobic exercise for a
12 duration of time typically in excess of 20 minutes, and
13 thereafter lies on a grounded cooling mat which is coupled
14 to the spine. In a preferred conditioning process, the
15 subject lies on a grounded cooling mat, and in another
16 embodiment of the invention, the cooling mat provides
17 application of a cooling temperature such as 38 to 68
18 degrees Fahrenheit to a large surface area of the spine and
19 surrounding tissues. In one embodiment of the invention,
20 the spinal region is cooled to a constant first temperature
21 such as 50 degrees Fahrenheit (from the range 38 to 68
22 degrees Fahrenheit), and the surrounding regions on either

1 side of the spinal region are cooled to a slightly lower
2 temperature than in the first temperature, and in a range
3 such as 38 to 60 degrees Fahrenheit, additionally with a
4 pulsating pressure having a cycle time in the range of 2
5 seconds, although it may be two or three times faster or
6 slower than this nominal cycle time.

7 Figure 3 shows a conditioning process with respect to
8 heart rate. The subject is at a base heart rate of 70
9 beats per minute (bpm) during a first interval from T0 to
10 T1, during which time the exercise machine equipment is
11 being configured and pressure cuffs applied, as was
12 described in steps 202, 204, 206 208 of figure 2. The
13 ramp-up phase described in step 210 and 212 is shown during
14 the interval from T1 to T2 (such as 20 minutes of exercise
15 with the exercise machine set to moderate resistance) of
16 figure 3, and the three repetitions of intense exertion (T2
17 to T3), such as provided by increased exercise resistance
18 by the exercise machine, and decreased exertion (T3 to T4)
19 such as by decreased exercise machine resistance are shown
20 as a first conditioning cycle (T2 to T4), second
21 conditioning cycle (T4 to T6), and third conditioning cycle

1 (T6 to T8). The cool-down cycle is shown in the interval
2 from T8 to T9.

3 Figure 4A shows an embodiment of the invention
4 suitable for providing cooling and compression in a
5 weightless environment, such as for use with a conditioning
6 or exercise station for astronauts. One of the problems of
7 space travel is the absence of gravity causes reduced
8 muscle use and exertion, leading to muscle atrophy and
9 loss of muscle tone. Additionally, the chronic absence of
10 venous back-pressure in the extremities because of the
11 absence of gravitational blood pressure causes the venous
12 valves to remain fully or partially open, which causes
13 retrograde and reduced venous blood flow. Under the
14 influence of earth's gravity, the venous valves of the
15 peripheral vascular system provide for enhanced circulation
16 of blood as the muscle groups periodically compress the
17 veins they enclose, thereby developing back-pressure in the
18 venous valves and enhancing circulation by displacing blood
19 during successive muscle contractions. The anatomical
20 terms proximal and distal refer to the relative position of
21 structures which are closer to the heart and further from
22 the heart, respectively. Without the influence of earth's

1 gravity, the gravitational blood pressure on the proximal
2 side of the venous valve is eliminated, which causes the
3 venous valves to remain partially open and for retrograde
4 blood flow through the venous valve and venous system to
5 occur. This reduced circulation rate in the lower
6 extremities is a particular problem, where chronic exposure
7 to the weightless environment can lead to compromised
8 circulation and associated circulatory diseases over the
9 long intervals of time associated with space travel.
10 Figure 4A shows a human subject 401 in a weightless
11 environment with a vascular stimulation system 400 which
12 includes a pressure/cooling controller 402, a gravity
13 simulation cuff 404, a thigh cuff 406, calf cuff 408, and
14 foot cuff 410. At least one of the cuffs 404, 406, 408,
15 410 is a pressure/cooling cuff, as was described for figure
16 1 and figure 1A. The controller 402 provides constant
17 temperature coolant, and return valves control the pressure
18 in each of P1, P2, P3, and P4 for the gravity stimulation
19 cuff 402, thigh cuff 406, calf cuff 408, and foot cuff 410,
20 respectively. Figures 4B and 4C show veins 450 in leg
21 extremities in a 1G environment where the upright gravity
22 blood pressure 452 in vein 450 assists in the closure of
23 venous valve 454. Muscle contractions in the muscles

1 surrounding the flexible vein 450 result in compressive
2 pressure 460 which overcomes this gravity blood pressure
3 452 of figure 4B and ejects blood 456 through the venous
4 valve 458 during a phase when it opens in response to the
5 muscle created back pressure 460, after which valve 458
6 closes as shown in figure 4B in response to the gravity
7 back pressure. The repetitive application of muscle
8 pressure 460 of figure 4C, such as from exercise, results
9 in the repetitive cycle of venous valve 458 opening in
10 response to muscle induced local blood pressure, and
11 gravity induced blood pressure 452 causing venous valve 454
12 to close as shown in figure 4B. A problem of 0G
13 weightlessness in space with regard to venous valve
14 operation is shown in figure 4D and 4E. The same vein 450
15 does not have any applied gravity force and does not
16 produce gravity blood pressure, which results in venous
17 valve 458 remaining open, resulting in retrograde flow 470
18 as shown in figure 4D. The problem of retrograde blood
19 flow in the extremities due to incomplete venous valve 470
20 closure is a significant long term risk in space flight, as
21 delivery of blood through the circulatory system is
22 compromised. The pressure cuffs of figure 4A can have
23 controlled application of a sequence of pressure

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1 manipulated in a variety of methods which simulate the
2 backpressure of gravity on the venous valves in a gravity
3 environment, thereby providing enhanced venous return blood
4 flow in weightless environments. Figure 4D shows the
5 effect of providing cuff pressure 474 in a dynamic manner
6 to keep venous valve 458 closed during a first interval,
7 and figure 4E shows a subsequent interval where distal
8 muscle pressure 482 is applied, which either overcomes cuff
9 pressure 474 shown in figure 4E, or alternatively the cuff
10 pressure is reduced when exercise motion is detected or
11 anticipated.

12 In another embodiment of the invention, each of the
13 pressure cuffs 406, 408, 410 include a series of
14 successively inflating chambers which provides a directed
15 pressure, as shown in figure 4G. Limb 490 is surrounded by
16 a pressurized cuff which has first inflating chamber 491 in
17 a distal position, second inflating chamber 492, third
18 inflating chamber 495 and fourth inflating chamber 497 in a
19 proximal position, which may be achieved by interconnecting
20 each chamber with a septum having an aperture for
21 controlled inflation. When first chamber 491 is
22 pressurized, second chamber 492 inflates to the region

1 shown by dashed line 494 and subsequently the third chamber
2 inflates to the region shown by dashed line 496, thereby
3 directing blood proximally. The operation of these cuffs
4 as successively inflating may be used for any individual
5 cuff 406, 408, or 410. In another embodiment of the
6 invention, the arrangement of chambers in cuffs 406, 408,
7 and 410 and the order of inflation may be used to simulate
8 natural movements such as the changing foot pressure of
9 walking in the case of cuff 410, or muscle contractions
10 associated with walking, in the case of cuffs 406 and 410.
11 Cuff 404 may operate independently for the singular purpose
12 of creating an initial backpressure to close the venous
13 valves, as shown in figure 4E. It is believed that the
14 operating range for venous compression should be within 50%
15 of a value which is 25% of the systolic blood pressure, and
16 an appropriate range of pressurized cuff pressures would be
17 18-28mm Hg.

18 Figure 5 shows one example of possible pressure
19 profiles for each of the cuffs for use in a weightless
20 environment. A single cycle is shown from start 520 to end
21 532, after which the cycle repeats at time 520. Gravity
22 cuff 404 is pressurized P1 at time 520, during which time

1 venous return pressure begins to build from interval 520 to
2 522. The other cuffs are pressurized from interval 522 to
3 524, released from 524 to 526, and then re-pressurized
4 until time 528, when the gravity cuff P1 releases, and the
5 pressure in cuffs P1, P2, P3 causes the blood to vigorously
6 return to the heart. The pressure cuffs are released at
7 time 530, and an interval of recovery 532 follows, after
8 which the cycle starts again at time 520. In one
9 embodiment of the invention, the cycle time from 520 to 532
10 is 30 seconds. In one embodiment of the invention for
11 improving circulation in a weightless environment, a
12 sequence of pressures is provided to cuffs 406, 408, 410
13 which simulates muscle contractions of walking, thereby
14 improving blood flow. In another embodiment of the
15 invention for improving circulation through the simulation
16 of walking in a weightless environment, a sequence of
17 pressures is provided to cuff 410, with a pressure first
18 applied to the ball of the foot followed by a pressure to
19 the heel of the foot. In another embodiment of the
20 invention, a sequence of cuff pressure is applied to cuffs
21 404, 406, 408, and 410 which improves blood flow in a
22 weightless environment by assisting in the closure of the
23 distal venous valves from cuff 404 by the short application

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1 of pressure in cuffs 404, 406, 408, 410 which closes the
2 venous valves in the manner shown in figure 4E. In another
3 embodiment of the invention, a first sequence of pressures
4 is provided which directs venous blood proximal from the
5 limb and towards the heart, and a second sequence of
6 pressures is provided which subsequently closes the venous
7 valves preventing venous distal retrograde flow.

8 In one embodiment of the invention for HGH generation
9 triggered by lactic acid from anaerobic exercise, the
10 pressurized and cooled cuffs carry a cooled liquid having a
11 temperature which is dynamically adjusted to provide
12 optimal vasoconstriction (temperature-induced reduction in
13 the diameter of the veins). A level of temperature-
14 associated vasoconstriction of the veins during exercise is
15 desired at a level which is sufficient to reduce oxygen
16 delivery to the muscles during exercise to signal a request
17 for the generation of HGH through muscle lactic acid
18 release. However, an excessive level of vasoconstriction
19 may result in muscle cramping, temperature related
20 discomfort, or hypothermia induced by the removal of heat
21 in excess of its generation in the muscles. Optimal
22 control of vasoconstriction may be achieved by dynamically

1 adjusting the coolant temperature to maintain a threshold
2 or a particular level of distal pulse (measurement of pulse
3 taken at a finger or toe) or in conjunction with a blood
4 pressure measurement to maintain a particular parametric
5 vasoconstriction value, where an increase in
6 vasoconstriction is indicated by either a decreased distal
7 pulse, or a reduction in distal blood pressure. In one
8 embodiment of the invention, the coolant is operated in the
9 low temperature range 38°F to 48°F for patients with a high
10 body mass, and in another embodiment of the invention, the
11 coolant is operated in the range 48°F to 68°F for patients
12 with a low body mass. In another embodiment of the
13 invention, the temperature of the coolant applied at
14 constant pressure to the cuffs is temporally varied, with
15 the coolant starting at a comparatively low end of the
16 temperature range during an interval of high exertion, as
17 measured by the output of an exercise machine (not shown),
18 or other external measurement of exertion, and the coolant
19 temperature is increased during an interval of reduced
20 exertion. In another embodiment of the invention, the
21 previously described coolant temporal temperature change is
22 applied either prior to or after the change in exertion to
23 achieve either improved comfort or improved HGH generation.

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1 In another embodiment of the invention, the extremity
2 pressurized cooled cuffs of figure 4 operate in conjunction
3 with exercise equipment (not shown) such that the extremity
4 cuff generates backpressure is determined by the timing and
5 coordination of figure 5.

6 Figure 6 shows another embodiment of the invention as
7 a cooling mat 606 with headrest 604 placed upon a support
8 surface such as a table 602 for a cooling system 600.
9 Figure 7 shows a plan view of mat 606, which has a series
10 of chilled water cooling channels which create elongate
11 isothermal profiles 702, 704, and 706 along a major axis
12 701 with a thermal gradient such that inner channel 702 has
13 the highest temperature and outer channel 706 has the
14 lowest temperature. This is shown such as through section
15 708 shown in the corresponding temperature profile 724 of
16 figure 7A, such that the inner elongate region may have a
17 temperature with a maximum of 68°F 722, and the outer
18 region may have a temperature with a minimum of 38°F 720.
19 Mat 606 may be constructed of a series of bladders with
20 restricted flow such that the coldest cooling water
21 circulates through inner bladders in region 702, and
22 circulates successively to outer region 706, with the flow

1 rate of the cooling water selected to achieve the desired
2 temperature profile such as shown in figure 7A.

3 Alternatively, the cooling mat 606 may achieve the
4 cooling profile shown in figure 7A through the unrestricted
5 flow of coolant through channels which match the profile
6 shown in figure 7, with a first channel 702 having an inlet
7 and outlet on opposite ends of the major axis 701, and the
8 other coolant channels 704 and 706 circulating coolant with
9 decreased temperature, as required by the desired
10 temperature profile shown in figure 7A. It is believed
11 that the coolant temperatures should be within the range of
12 38-58°F, with the coolant closest to the spinal column in
13 channel 702 at an elevated temperature compared to the
14 muscular regions on either side of the spine in regions 704
15 and 706.

16 The description of the embodiments of the invention
17 are not intended to limit the scope of the invention, but
18 to illustrate a particular best mode of operation of the
19 invention. The steps of the invention can be practiced in
20 combination or separately without loss of benefit. In
21 particular, the operational pressure may be set to a fixed
22 threshold or an adjustable threshold, and the measurement

1 of systolic blood pressure may be performed once or over
2 several iterations during the exercise cycle.

1

2 I claim:

3 1) A process for generation of human growth hormone in
4 a subject having a systolic blood pressure, the process
5 operative on one or more pressurizable cuffs developing an
6 operational pressure by pumping a chilled coolant from a
7 chilled coolant reservoir through said pressurized cuff and
8 thereafter through a regulation valve for each said
9 pressurized cuff which controls the return of chilled
10 coolant to the coolant reservoir, each said pressurized
11 cuff additionally having a transducer to measure subject
12 blood flow, the process having:

13 a first step of placing subject extremities in said
14 pressurizable cuff;

15 a second step of using said transducer to measure a
16 systolic blood pressure by varying at least one said
17 regulation valve associated with said cuff;

18 a third ramp-up step during a subject exertion
19 interval whereby said pressurized cuff has a ramp-up
20 coolant pressure P in the range of 33% to 220% of said
21 measured systolic blood pressure, said pressurized cuff
22 developing said ramp-up coolant pressure by control of said

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1 regulation valve of said cuff which returns said coolant to
2 said coolant reservoir, said pressurized coolant at a
3 temperature and pressure sufficient to reduce circulation
4 in a subject;

5 a fourth step of a sequence of N conditioning cycles,
6 each conditioning cycle having an intense exertion interval
7 performed by the subject followed by a reduced exertion
8 interval performed by the subject, the intense exertion
9 interval requiring substantially greater subject exertion
10 than the ramp-up subject exertion;

11 a fifth cool-down step of removing pressure from said
12 pressurized cuffs by opening said regulation valves, and
13 thereafter placing the subject in a substantially
14 horizontal position and applying a cooled liquid contained
15 in a flexible bladder to a spinal region for cooling of a
16 patient cerebral spinal fluid (CSF).

17

18 2) The method of claim 1 where said subject is a
19 human.

20

1 3) The method of claim 1 where said chilled coolant
2 delivered by said pump to said pressurized cuffs has a
3 temperature of 38 to 68 degrees Fahrenheit.

4
5 4) The method of claim 1 where said third step
6 pressure P is periodically recomputed from a new value of
7 systolic blood pressure.

8
9 5) The method of claim 1 where said subject is a human
10 and at least two of said pressurized cuffs are applied to
11 the legs.

12
13 6) The method of claim 1 where said subject is a human
14 and at least two of said pressurized cuffs are applied to
15 the arms.

16
17 7) The method of claim 1 where said fifth step bladder
18 has a central elongate region with an incrementally lower
19 temperature than a region which surrounds said elongate
20 region.

1 8) The method of claim 7 where said fifth step bladder
2 central elongate region is at a temperature between 38 to
3 68 degrees Fahrenheit and said region which surrounds said
4 elongate region is at a temperature which is below that of
5 said central elongate region.

6
7 9) The method of claim 1 where said first step
8 systolic blood pressure measurement causes a regulation
9 valve associated with a particular pressure cuff to close
10 until said transducer no longer detects a blood flow, said
11 systolic pressure being the pressure measured at the
12 regulation valve inlet at the time said blood flow is no
13 longer detected.

14
15 10) A process for generation of human growth hormone
16 in a subject having a systolic blood pressure, the process
17 operative on one or more pressurized cuffs developing said
18 operational pressure by pumping a chilled coolant from a
19 chilled coolant reservoir through said pressurized cuff and
20 thereafter through a regulation valve for said pressurized
21 cuff which controls the return of chilled coolant to the
22 coolant reservoir, each said pressurized cuff additionally

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1 having a transducer to measure subject blood flow, the
2 process having:

3 a first step of placing subject extremities in said
4 pressurized cuff;

5 a second ramp-up step during a subject exertion
6 interval whereby said pressurized cuff has a ramp-up
7 coolant pressure P in the range of 33% to 220% of said
8 measured systolic blood pressure, said pressurized cuff
9 developing said ramp-up coolant pressure by control of said
10 regulation valve of said cuff which returns said coolant to
11 said coolant reservoir, said pressurized coolant at a
12 temperature and pressure sufficient to reduce circulation
13 in a subject;

14 a third step of a sequence of N conditioning cycles,
15 each conditioning cycle having an intense exertion interval
16 performed by the subject followed by a reduced exertion
17 interval performed by the subject, the intense exertion
18 interval requiring substantially greater subject exertion
19 than the ramp-up subject exertion;

20 a fourth cool-down step of removing pressure from said
21 pressurized cuffs by opening said regulation valves, and
22 thereafter placing the subject in a substantially

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1 horizontal position and applying a cooled liquid contained
2 in a flexible bladder to a spinal region for cooling of a
3 patient cerebral spinal fluid (CSF).
4

5 11) The method of claim 10 where said subject is a
6 human.
7

8 12) The method of claim 10 where said chilled coolant
9 delivered by said pump to said pressurized cuffs has a
10 temperature of 38 to 68 degrees Fahrenheit.
11

12 13) The method of claim 10 where said second step
13 pressure varies with systolic blood pressure.
14

15 14) The method of claim 10 where said subject is a
16 human and at least two of said first step pressurized cuffs
17 are applied to the legs.
18

1 15) The method of claim 10 where said subject is a
2 human and at least two of said pressurized cuffs are
3 applied to the arms.

4
5 16) The method of claim 10 where said first step
6 systolic blood pressure measurement causes a regulation
7 valve associated with a particular pressure cuff to close
8 until said transducer no longer detects a blood flow, said
9 systolic pressure being the pressure measured at the
10 regulation valve inlet.

11
12
13 17) A method for generating increased HGH production
14 in a human subject, the method having:

15 a first step where a human subject exercises
16 aerobically for 20 minutes or more;

17 a second step where said human subject is placed on a
18 substantially horizontal surface with a liquid cooled
19 bladder circulating a liquid thermally coupled to said
20 human subject spine and sufficient to cool the CSF of said
21 human subject.

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1

2 18) The method of claim 17 where said flexible
3 bladders are coupled to a local ground potential.

4

5

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