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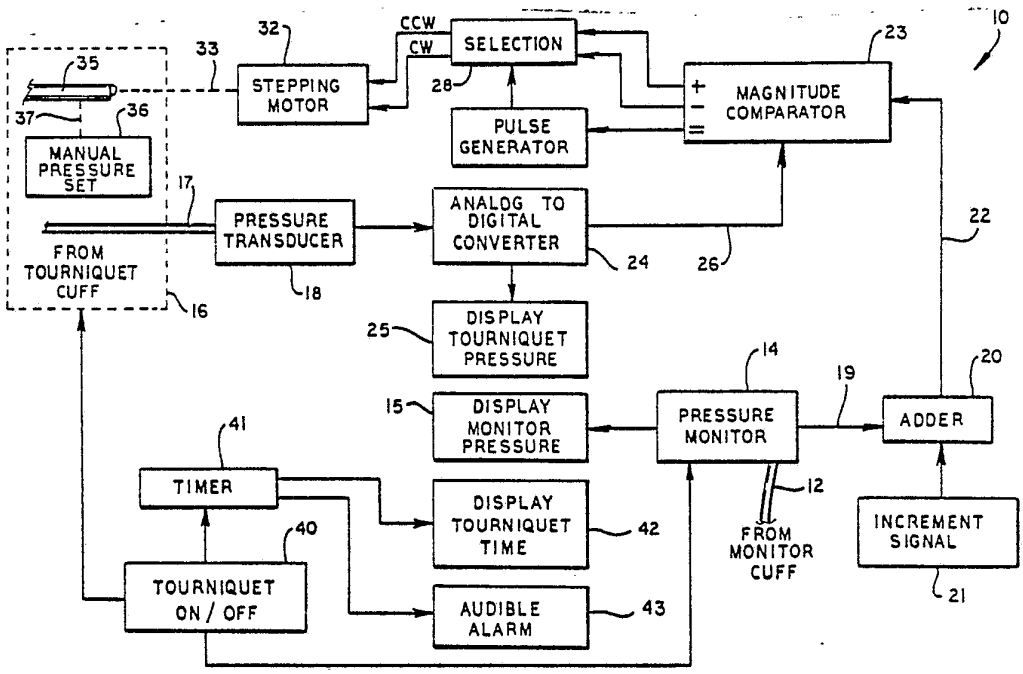
(54) Title: PRESSURE-RESPONSIVE TOURNIQUET




(57) Abstract

An automatic pneumatic tourniquet apparatus for occluding blood flow in a person's limb includes an adjustable pneumatic tourniquet (16) operable to vary the pressure applied about the limb, a systolic blood pressure monitor (14) and a control circuit responsive to changes in the blood pressure measured by the pressure monitor to operate the tourniquet to maintain the pressure about the limb at a level greater than the person's blood pressure by a predetermined amount. The apparatus maintains tourniquet pressure at a minimum acceptable level and thereby minimizes nerve damage caused by the compression of the tourniquet on nerve tissues over long periods.

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# "PRESSURE-RESPONSIVE TOURNIQUET"

## Technical Field

The present invention relates to tourniquets utilized to provide a bloodless operative field during surgery on the extremities of the body, and more particularly relates to a pressure-responsive, self-adjusting pneumatic tourniquet.

## Background Art

During surgery on the upper and lower extremities of the body, it is highly desirable to provide a bloodless field in order to shorten the operating time and thus decrease the surgical and anesthetic risk to the patient. In many operative procedures, it is necessary to cut off essentially all blood flow in a limb by using a tourniquet. Pneumatic tourniquets, such as the Kidde pneumatic tourniquet described in U.S. Patents 3,085,599 and 2,884,941, have been widely used for this purpose. Fluid, such as compressed air, is supplied to a cuff surrounding the limb at a manually-set arbitrary level of 300-500 mm Hg for a recommended duration of up to one and one-half hours.

Many complications associated with the use of pneumatic tourniquets have been reported in medical

literature. The most frequently reported have been nerve palsies arising from a slowing resolving nerve compression syndrome secondary to the use of the pneumatic tourniquet. Such nerve palsies can greatly delay the patient's rehabilitation. Tourniquet-related problems have been reported in the following articles: Rorabeck, "Tourniquet-Induced Nerve Ischemia: An Experimental Investigation", THE JOURNAL OF TRAUMA, Vol. 20, No. 4, pages 280-286 (1980); Weingarden, Louis and Waylonis, "Electromyographic Changes in Postmeniscectomy Patients", JAMA, Vol. 241, No. 12, pages 1248-1250 (March 23, 1979). It has been concluded that the fluid pressure supplied to the cuff of a pneumatic tourniquet should be maintained as low as possible with respect to the patient's systolic blood pressure.

Measurement of a patient's blood pressure is possible using non-invasive monitoring equipment. Such monitoring equipment typically uses one or two pressure cuffs, as shown in U.S. Patents 2,193,945, 3,779,235 and 4,167,181. However, there has been no suggestion in the art that the pressure applied by a tourniquet cuff be automatically adjusted in response to changes in a patient's blood pressure to maintain the tourniquet cuff pressure at the minimum acceptable value above the patient's blood pressure.

## Summary of the Invention

The present invention provides a method and apparatus for automatically maintaining the pressure applied by a tourniquet cuff at a level selected to minimize nerve damage to each individual patient. Generally described, an automatic tourniquet apparatus according to the present invention for occluding blood flow in a person's limb comprises a tourniquet

operable to adjust the pressure applied about the limb by the tourniquet, pressure monitoring means for measuring the person's blood pressure, and means responsive to changes in the person's blood pressure for operating the tourniquet to maintain pressure about the limb at a level greater than the person's blood pressure by a predetermined amount. The method of occluding blood flow in a person's limb according to the present invention comprises the steps of applying pressure about the limb with an adjustable tourniquet, monitoring the person's blood pressure, and, responsive to changes in the person's blood pressure, adjusting the tourniquet to maintain application of pressure about the limb at a level greater than the person's blood pressure by a predetermined amount.

The tourniquet utilized in an apparatus embodying the invention preferably comprises a pneumatic tourniquet operable by inflating a cuff surrounding the person's limb, and the pressure monitoring means preferably comprises a non-invasive cuff means for measuring systolic pressure. The means for operating the tourniquet in response to changes in blood pressure preferably comprises a means for measuring the pressure applied by the tourniquet, comparator means for comparing the pressure applied by the tourniquet with the person's blood pressure, and means responsive to the pressure applied by the tourniquet being greater than the person's blood pressure by more or less than the predetermined amount for lowering or raising, respectively, the pressure applied by the tourniquet. Variations in the person's blood pressure can occur during surgery as a result of reaction to anesthesia or surgical stimulation.

Thus, it is an object of the present

invention to provide an automatic tourniquet apparatus and method which minimizes nerve damage caused by the compressive force of the tourniquet about a limb.

It is a further object of the present invention to provide an automatic tourniquet apparatus which measures a person's systolic blood pressure and maintains pressure applied about a limb by said tourniquet at a predetermined level above the systolic blood pressure.

It is a further object of the present invention to provide a method and apparatus for occluding blood flow in a person's limb in an individualized manner for any person.

It is a further object of the present invention to provide an automatic tourniquet apparatus that is less subject to operator error and therefore safer than prior manually-operated tourniquets.

Other objects, features and advantages of the present invention will become apparent upon reading the following detailed description of a preferred embodiment, when taken in conjunction with the drawing.

## Brief Description of the Drawing

The Figure is a diagrammatic representation of an automatic tourniquet apparatus embodying the present invention.

## Detailed Description

Referring now in more detail to the drawing, the Figure shows a diagrammatic representation of circuit elements of an automatic tourniquet apparatus 10 embodying the present invention. A fluid line 12 leads from a pressure cuff (not shown) of conventional construction to a non-invasive pressure monitor 14.

The pressure monitor 14 preferably comprises the unit sold by Critikon, Inc. of Tampa, Florida under the trademark "DYNAMAP" Model 845. The DYNAMAP monitor measures systolic and diastolic pressure, mean arterial pressure and heart rate using the oscillometric method. The circuitry of the pressure monitor 14 causes the cuff to be inflated sufficiently to occlude the artery, and then deflates the cuff incrementally while monitoring pulses introduced into the cuff by pulsations of the arteries. The monitor 14 determines where such pulsations increase, peak and decrease, and interprets such data to provide digital displays of the blood pressure and pulse measurements. A digital systolic display 15 displays the parameter relevant to operation of the present invention.

The apparatus shown in the Figure also includes a pneumatic tourniquet 16, elements of which are shown diagrammatically in the figure. The pnuematic tourniquet 16 is preferably a Kidde pneumatic tourniquet as shown and described in U.S. Patent 3,085,599, issued April 16, 1963 to J. Kronheim. Said patent is expressly incorporated herein by reference in its entirety. The Kidde pneumatic tourniquet includes a conventional pneumatic cuff which surrounds the limb upon which surgery will be performed and a pressure regulator (not shown in the present drawing). A fluid line 17 from the tourniquet cuff is connected to a conventional pressure transducer 18. The pressure transducer 18 provides an analog output which is digitized by analog to digital converter 24, the output of which represents the pressure within the tourniquet cuff and is displayed by a digital tourniquet pressure display 25.

An electrical line 19 is connected to the

digital systolic pressure output of the pressure monitor 14, and carries such signal to an adder 20. An increment signal generator 21 provides another input to the adder 20. Increment signal generator 21 may be embodied by any switching arrangement, such as a plurality of thumbwheel switches, which provides an appropriately scaled binary number to adder 20. The signal supplied by the increment signal generator 21 can be manually adjusted, and represents the predetermined amount by which the tourniquet pressure about the limb will be maintained above the systolic blood pressure measured by the pressure monitor 14. The recommended increment is 100-150 mm Hg. The cuff connected to the line 12 for blood pressure measurement can be placed around any limb which will provide an accurate measurement of the person's blood pressure. Preferably, the blood pressure is measured on a limb other than the limb upon which surgery is being performed, so that the tourniquet on the same limb cannot affect the accuracy of the blood pressure readings.

The output of the analog to digital converter 24 is connected along bus 26 to a magnitude comparator 23, the other input of which is the output signal from the adder 20 which is connected to the comparator 23 along bus 22. The comparator 23 is a digital device of well known construction which compares the two input signals and provides one of three output signals depending on the relative magnitudes of the signals being compared. If the signal along bus 22 from the adder 20, representing the sum of the systolic blood pressure and the increment signal, is greater than the signal on bus 26 representing the pressure within the tourniquet cuff, the magnitude comparator 23 provides a "+" output. If

the signal along bus 26 is greater than the signal along bus 22, then the comparator 23 provides a "-" output signal. If the signals along buses 22 and 26 are equal, the comparator 23 provides an "=" output signal. Magnitudinal comparator 23 may be constructed in a known manner by using one or more integrated circuit digital magnitude comparators, for example, the type 4063 CMOS circuit currently manufactured by RCA.

The "+" and "-" outputs of the comparator 23 are input to a selector 28 which is also of conventional construction. The selector is activated at regular small intervals by pulses from a pulse generator 29 which is constructed to provide its regular pulses throughout operation of the apparatus 10 unless disabled. The pulse generator 29 is disabled when the comparator 23 provides an "=" output. Pulse generator 29 is preferably embodied by an oscillator, the output of which is gated by the "=" output of comparator 23. The selector 28 provides output signals in either a clockwise ("CW") or a counter clockwise ("CCW") mode to a digital stepping motor 32. The stepping motor 32 is connected mechanically by a diagrammatically shown connection 33 to a shaft 35 which is the shaft of the pneumatic tourniquet 16 rotatable to operate the pressure regulator to change the pressure within the tourniquet cuff. The clockwise output of the selector 28 activates the motor 32 to rotate the shaft 35 a small amount in the clockwise direction so as to decrease the pressure applied by the tourniquet 16. The counter clockwise output of the selector 28 activates the motor 32 to rotate the shaft 35 in the counter clockwise direction so as to increase the pressure applied by the tourniquet 16. The shaft 35 is also

rotatable manually by a manual pressure set control 36 which is connected mechanically to the shaft 35 by a mechanical connection 37 diagrammatically shown in the Figure.

The apparatus 10 includes a tourniquet on/off switch 40 which provides power to the components of the apparatus 10 and activates a timer 41 which accumulates the time that the tourniquet has been asserting pressure around the person's limb. The output of the timer 41 is connected to a digital display 42 of the duration of tourniquet application, and also to an audible alarm 43 constructed to provide an audible signal at predetermined intervals, such as every fifteen minutes of tourniquet application.

In operation of a tourniquet apparatus 10 according to the present invention, the monitor cuff and the tourniquet cuff are applied to limbs of the person and the surgical area is prepped, draped and exsanguinated. The manual pressure set control 36 is adjusted to a value believed to be near the desired increment above the person's blood pressure, and the increment signal generator 21 is adjusted to provide the desired pressure increment signal to the adder 20. The switch 40 is then turned on, initiating operation of the timer 41 and the time display 42. Pressure is provided to the pneumatic tourniquet 16, in the conventional manner, and that pressure is measured by the pressure transducer 18 and displayed on the digital display 25. Power is at the same time supplied to the pressure monitor 14, which begins the series of steps required to measure the person's systolic blood pressure and to display the pressure on the digital display 15. The pressure monitor 15 measures the systolic blood pressure at selected intervals as often as once per minute. The digital

systolic pressure signal is added to the increment signal by the adder 20, and the magnitude comparator 23 compares the magnitudes of the signal from the adder 20 and the signal representing the tourniquet cuff pressure measured by the transducer 18. If the tourniquet cuff pressure is not greater than the systolic blood pressure by at least the amount of the predetermined increment signal, then the signal along bus 22 will be greater than the signal along bus 26, and the magnitude comparator 23 will provide a "+" output to the selector 28. Upon the next pulse from the pulse generator 29, the selector 28 provides a counter clockwise output to the stepping motor 32. This causes the shaft of the stepping motor 32 to rotate counter clockwise a very short rotational distance, and thereby through the mechanical connection 33 causes the shaft 35 to rotate and operate the pressure regulator of the pneumatic tourniquet 16 to increase the pressure in the tourniquet cuff. If the increase in pressure thus obtained does not equalize the signals input to the magnitude comparator 23, the output of the comparator 23 will remain "+" and the selector 28 upon the next pulse of the pulse generator 29 will again cause the stepping motor 32 to incrementally rotate to increase the tourniquet cuff pressure another step.

When the magnitude of the signals along buses 22 and 26 becomes equal, the magnitude comparator 23 will provide an "=" output, disabling the pulse generator 29. Under this condition, the selector 28 will not be activated to step the stepping motor 32, and the pressure in the tourniquet cuff will remain unchanged. If, when the pressure monitor 14 makes a subsequent determination of systolic blood pressure representing a change in the person's

systolic blood pressure, the signal along line 22 will change by the amount of the change in systolic blood pressure. If, for example, the change in the signal along bus 22 represents a reduction in blood pressure, then the signal along bus 22 will be less than the signal along bus 26, and the pressure in the tourniquet cuff will be greater than the systolic blood pressure by more than the amount of the increment signal. This will cause the magnitude comparator 23 to provide a "-" output, and the pulse generator 29 will again be enabled to activate the selector 28. In response to an activating pulse from the pulse generator 29 and a "-" output from the comparator 23, the selector 28 will provide a clockwise signal output to the stepping motor 32, stepping the shaft of the motor 32 in a clockwise direction and thereby causing the shaft 35 of the pressure regulator of the pneumatic tourniquet 16 to be rotated incrementally so as to slightly decrease the pressure in the tourniquet cuff. This will be repeated automatically until the signals to the comparator 23 along buses 22 and 26 are equalized.

It will thus be seen that through the action of the magnitude comparator 23, the selector 28, the pulse generator 29 and the stepping motor 32, the compression exerted by the tourniquet cuff about the limb is continually monitored and maintained at a predetermined pressure above the systolic blood pressure of the patient. The predetermined amount is determined by the setting of the increment signal which is combined with the systolic blood pressure signal by the adder 20. An automatic tourniquet apparatus 10 embodying the present invention thus responds to changes in the patient's blood pressure which may occur during surgery for reasons such as

reaction to anesthesia or surgical stimulation. If the pressure in the tourniquet cuff were to remain at a fixed value, as has been the case in prior pneumatic tourniquet systems, a drop in the patient's blood pressure would unnecessarily increase the differential between the pressure of the tourniquet cuff and the blood pressure. By maintaining a desired differential, the present invention minimizes nerve damage caused by the compression of the tourniquet on nerve tissues.

In addition to individualizing the tourniquet cuff pressure for each patient as determined by their own physiological needs, the present invention will minimize or eliminate accidents that have occurred from time-to-time as the result of human error by the misreading or misadjustment of manual controls of present pneumatic tourniquets. If the tourniquet cuff pressure is unintentionally set at an extremely high value, the resulting damage to the limb below the tourniquet can result in a need for limb amputation. This would not happen to a patient on which the automatic tourniquet of the present invention is used. Further advantages include a more accurate accounting of actual tourniquet lapsed time, and reductions in hospital and patient costs through the elimination of long rehabilitative processes now necessitated by the slow regeneration of damaged nerve tissue.

It will be understood by reference to the drawing that the apparatus 10 can be constructed as a single unit or as a modular unit utilizing commercially available units for the pressure monitor and pneumatic tourniquet components. It is preferable to provide a central control panel including the on/off switch 40, the monitor pressure display 15, the

tourniquet pressure display 25, the tourniquet time display 42, the audible alarm 43, and adjustment controls for the increment signal generator 21.

While the preferred embodiment shown herein uses digital control techniques, it will be appreciated that embodiments of the present invention using conventional analog servo mechanisms may be constructed.

While this invention has been described in detail with particular reference to a preferred embodiment thereof, it will be understood that variations and modification can be effected within the spirit and scope of the invention as described hereinbefore and as defined in the appended claims.

## Claims

1. An automatic tourniquet apparatus for occluding blood flow in a person's limb, comprising:

a tourniquet operable to adjust the pressure applied about said limb by said tourniquet;

pressure monitoring means for measuring said person's blood pressure; and

means responsive to changes in said person's blood pressure for operating said tourniquet to maintain pressure about said limb at a level greater than said person's blood pressure by a predetermined amount.

2. The apparatus of Claim 1, wherein said tourniquet comprises a pneumatic tourniquet operable by inflating a cuff surrounding said person's limb.

3. The apparatus of Claim 1, wherein said pressure monitoring means comprises a non-invasive cuff means for measuring systolic pressure.

4. The apparatus of Claim 1, wherein said means for operating said tourniquet comprises:

means for measuring the pressure applied by said tourniquet;

comparator means for comparing the pressure applied by said tourniquet with said person's blood pressure; and

means for (a) lowering the pressure applied by said tourniquet in response to said pressure applied by said tourniquet being greater than said person's blood pressure by more than said predetermined amount, and (b) raising the pressure applied by said tourniquet in response to said pressure applied by said tourniquet being less than said person's blood pressure or greater than said person's blood pressure by less than said predetermined amount.

5. The apparatus of Claim 1 further comprising means for varying said predetermined amount of pressure above said person's blood pressure.

6. A method of occluding blood flow in a person's limb comprising the steps of:

applying pressure about said limb with an adjustable tourniquet;

monitoring said person's blood pressure; and

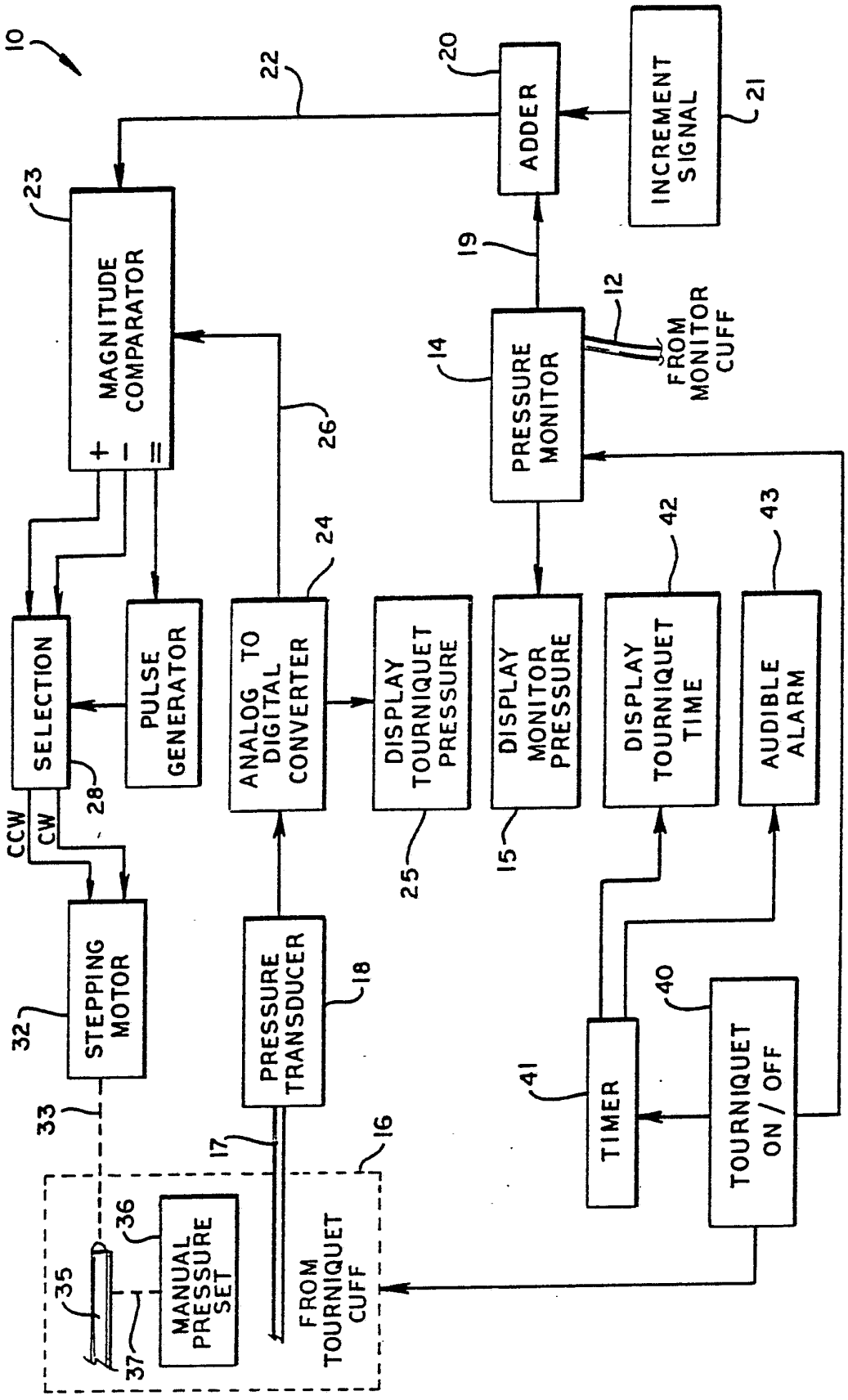
responsive to changes in said person's blood pressure, adjusting said tourniquet to maintain application of pressure about said limb at a level greater than said person's blood pressure by a predetermined amount.

7. The method of Claim 6, wherein said step of adjusting said tourniquet comprises the steps of:

measuring the pressure applied by said tourniquet;

comparing the pressure applied by said tourniquet with said person's blood pressure; and

responsive to said pressure applied by said tourniquet being greater than said person's blood pressure by more or less than said predetermined amount, lowering or raising, respectively, the pressure applied by said tourniquet.



# INTERNATIONAL SEARCH REPORT

International Application No PCT/US82/01317

## I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

INT. CL.3 A61B 17/12

U.S. CL. 128/327

## II. FIELDS SEARCHED

Minimum Documentation Searched [4]

| Classification System | Classification Symbols |
|---|---|
| US | 128/327, 682 |

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

## III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

| Category * | Citation of Document, [16] with indication, where appropriate, of the relevant passages [17] | Relevant to Claim No. [18] |
|---|---|---|
| Y | N, "Complications Of And Improvements In Pneumatic Tourniqvets Used In Surgery"; MEDICAL INSTRUMENTATION Vol.15,No.4, McEwen, Published July-August 1981, pp.253-257 | 1-5 |
| Y | GB, A, 1,253,501 Published 17 November 1971 IBM | 1-5 |
| Y,P | US, A, 4,321,929 Published 30 March 1982 Lemelson et al | 1-5 |

* Special categories of cited documents: [15]

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

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"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)

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"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

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"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

## IV. CERTIFICATION

| Date of the Actual Completion of the International Search [2] | Date of Mailing of this International Search Report [2] |
|---|---|
| 17 November 1982 | 23 DEC 1982 |
| International Searching Authority [1] | Signature of Authorized Officer [20] |
| ISA/US | Michael H. Thaler |

Form PCT/ISA/210 (second sheet) (October 1981)

**FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET**

**V. [X] OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [10]**

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. [X] Claim numbers 6-7, because they relate to subject matter [12] not required to be searched by this Authority, namely:

METHODS FOR TREATMENT OF THE HUMAN OR ANIMAL BODY FOR SURGERY OR THERAPY, AS WELL AS DIAGNOSTIC METHODS (RULE 39.1(iv)).

2. [ ] Claim numbers _____, 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 [13], specifically:

**VI. [ ] OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [11]**

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 of the international application.

2. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. [ ] 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 claim numbers:

4. [ ] As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

[ ] The additional search fees were accompanied by applicant's protest.

[ ] No protest accompanied the payment of additional search fees.