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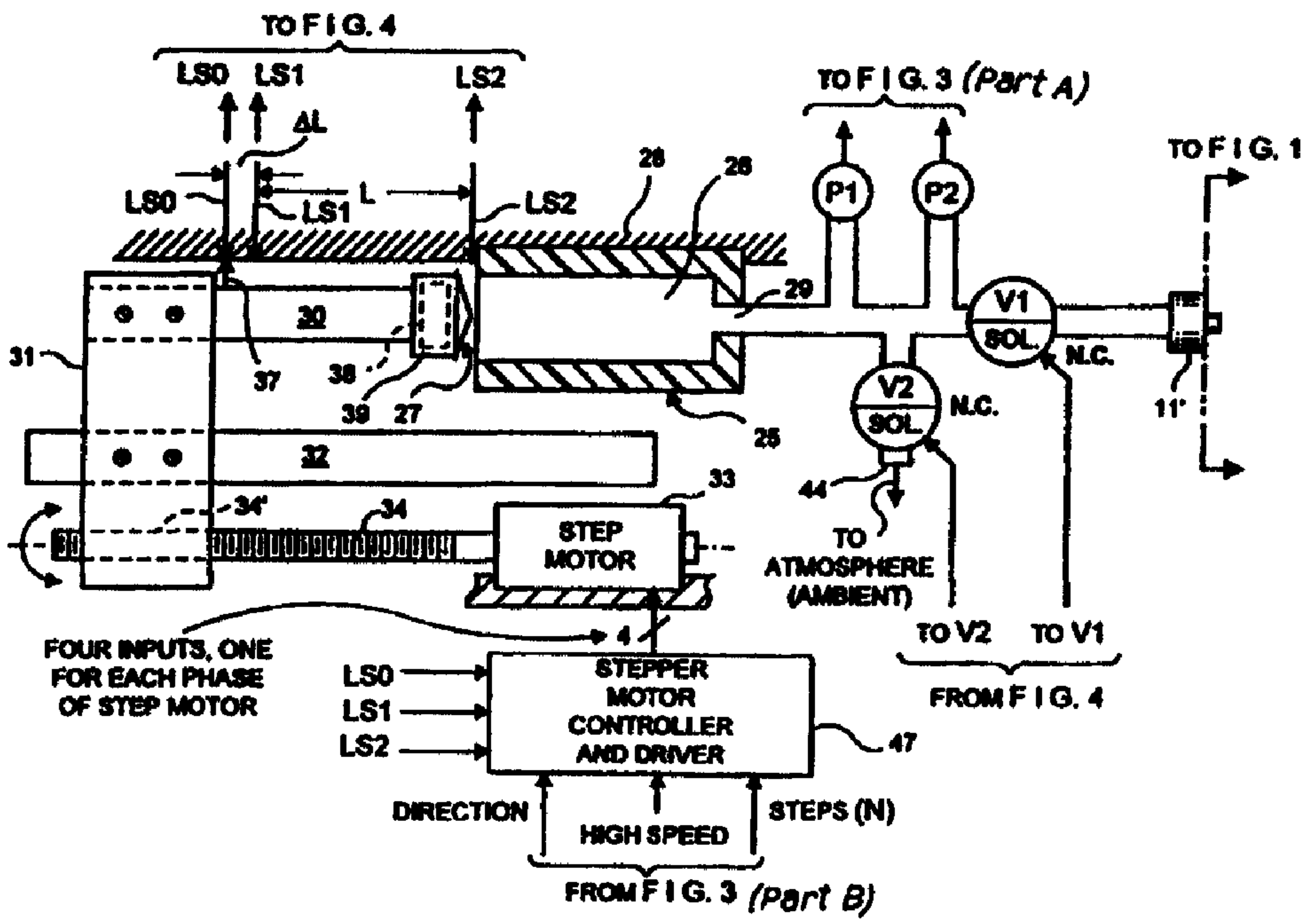
(54) **SURVEILLANCE ET COMMANDE D'UN MASQUE ENDOTRACHEAL**

(54) **MONITORING AND CONTROL FOR A LARYNGEAL MASK AIRWAY DEVICE**



(57) L'invention porte sur un moteur réversible actionnant mécaniquement le piston (27) d'une seringue à air (26) pneumatiquement reliée au ballonnet (19) d'étanchéité gonflable/dégonflable d'un masque (12) endotrachéal (LMA) appliqué à un patient en cours de ventilation et/ou d'anesthésie. Idéalement: (i) l'air de l'extrémité de la seringue (26), plus (ii) l'air contenu dans le ballonnet (19) du LMA (12), plus (iii) l'air contenu dans leurs interconnections, constitue un volume sensiblement constant commun aux trois parties, mais automatiquement commuté par les déplacements du piston (27) afin que la pression de l'air dans ledit volume

(57) A reversibly operable motor is mechanically connected to automatically position the piston (27) of an air syringe (26) that is pneumatically connected to the inflatable/deflatable seal ring or cuff (19) of a laryngeal mask airway device (LMA) (12) that is installed in a patient, who is being ventilated and/or anaesthetized via the airway of the LMA device (12). Ideally, (i) the air at the head end of the syringe (26), plus (ii) the air contained in the inflatable cuff (19) of the LMA (12), plus (iii) the air contained in their interconnection, is a "substantially constant" volume which is shared at these three locations but which is automatically shifted by

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s'ajuste si nécessaire sur un niveau prédéterminé de valeur de consigne. L'invention porte également sur différents instruments (10), dont certains commandés par microprocesseur, suivant en continu les formes de réponse du système aux anomalies constatées, et transmettant à l'anesthésiste des alarmes sonores et visuelles.

piston (27) displacement, such that air pressure in the substantially constant volume is caused to correct as necessary for conformance to a predetermined level of set-point pressure. Various instrumentalities (10), including microprocessor-controlled instrumentalities, continuously monitor patterns of system response to observed pattern abnormality, with audibly and visually reported warnings to the anaesthetist.

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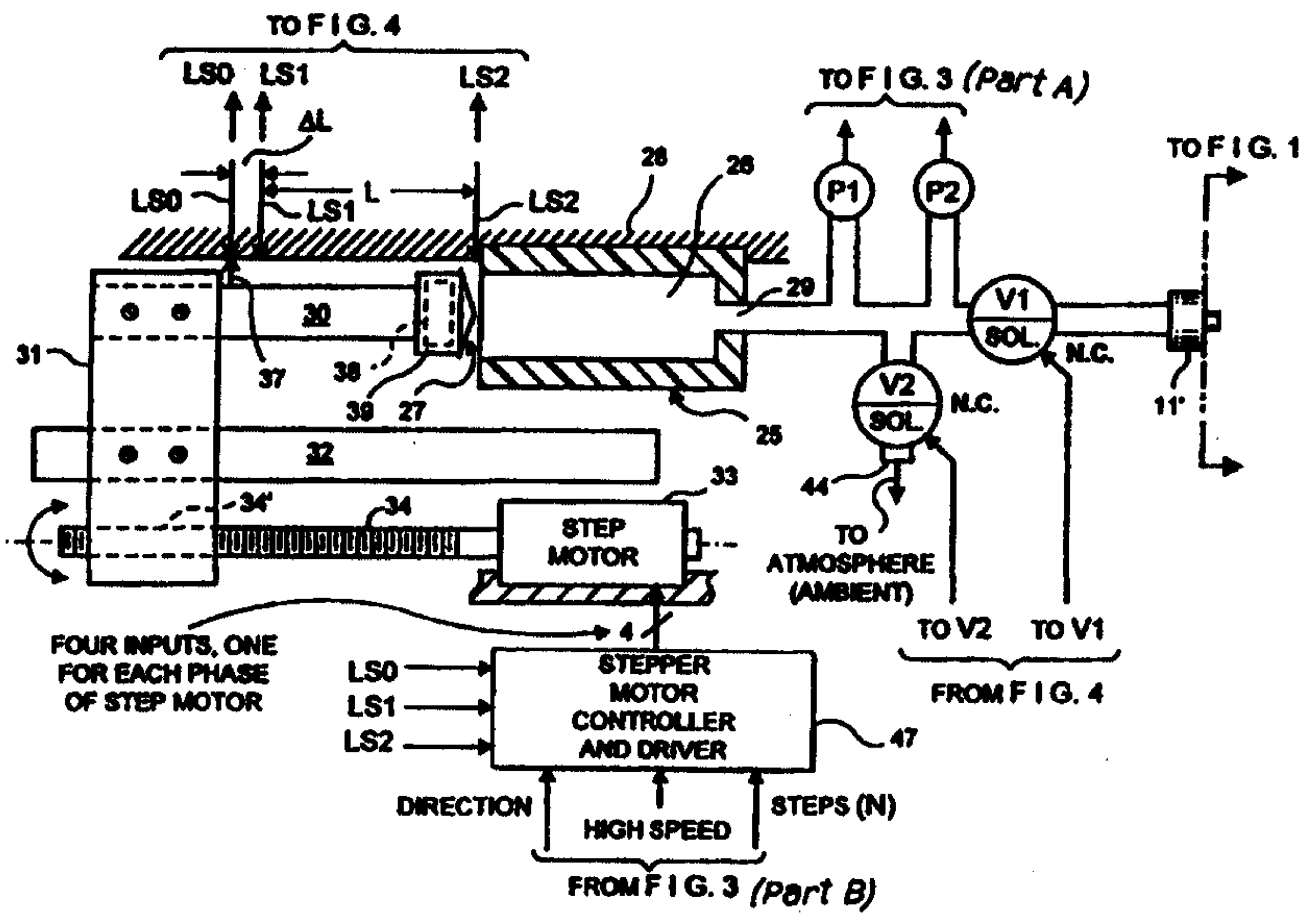
(54) Title: MONITORING AND CONTROL FOR A LARYNGEAL MASK AIRWAY DEVICE



(57) Abstract

A reversibly operable motor is mechanically connected to automatically position the piston (27) of an air syringe (26) that is pneumatically connected to the inflatable/deflatable seal ring or cuff (19) of a laryngeal mask airway device (LMA) (12) that is installed in a patient, who is being ventilated and/or anaesthetized via the airway of the LMA device (12). Ideally, (i) the air at the head end of the syringe (26), plus (ii) the air contained in the inflatable cuff (19) of the LMA (12), plus (iii) the air contained in their interconnection, is a "substantially constant" volume which is shared at these three locations but which is automatically shifted by piston (27) displacement, such that air pressure in the substantially constant volume is caused to correct as necessary for conformance to a predetermined level of set-point pressure. Various instrumentalities (10), including microprocessor-controlled instrumentalities, continuously monitor patterns of system response to observed pattern abnormality, with audibly and visually reported warnings to the anaesthetist.

MONITORING AND CONTROL FOR A LARYNGEAL MASK AIRWAY DEVICE

BACKGROUND OF THE INVENTION

This invention relates to apparatus useful for controlling and/or monitoring the inflation pressure within a laryngeal mask airway (LMA) device and to a method and means for monitoring a patient's welfare by way of fluctuations in that inflation pressure.

LMA devices are now well known and are in widespread use in patient care, both during and after surgical procedures and during procedures that involve maintaining a clear airway. Such devices and their construction and use are described in various patent publications, for example, British Patent No. 2,205,499 and United States Patent Nos. 4,509,514; 5,303,697; 5,241,956; and 5,282,464.

That such LMA devices are well accepted tools in patient care is borne out by simple statistics. For example, it is estimated that such devices are used in approximately 50 percent of all operative procedures requiring the use of general anaesthetic in the UK, and their use is becoming increasingly accepted elsewhere in Europe and in the USA.

Basically, an LMA device comprises an airway tube that is sized and curved for general conformance with a patient's airway; the airway tube extends from a proximal end that is external to the patient, to a distal end that carries mask structure in the form of a bowl or backing plate which faces and covers the patient's laryngeal inlet and which is continuously surrounded by a flexible ring or cuff that is selectively inflatable for resiliently sealed conformance to body structure around the laryngeal inlet. In use, the LMA is first fully deflated to aid its insertion and is then passed through the patient's mouth and throat into its correct position, with the mask over the laryngeal opening. The inflatable cuff surrounding the mask structure is then inflated to form a seal between the mask and the laryngeal opening. The air pressure with which the cuff is inflated forces the rear of the bowl of the mask against firm tissues at the back of the throat to maintain the device in place and to retain the seal. In this way, the device forms an open airway through which the patient's lungs can be ventilated.

Such LMA devices have proved to be both sturdy in construction and relatively straightforward to use, even by paramedics after the necessary training; however, if a mask is wrongly inserted, a reliable airway is not in fact formed and the patient's lungs are not then properly ventilated. In addition, the soft compliant silicone material of the cuff has been known to absorb nitrous oxide from anaesthetic gas mixture thereby increasing the pressure within the cuff, and the cuff itself may occasionally develop leakage causing its internal pressure to decrease. Also, it has been found that too high an inflation pressure will cause the cuff to restrict the blood supply to the mucosa overlying the muscles around the laryngeal inlet, and prolonged use of an LMA device in such circumstances can lead to tissue necrosis.

It has recently been proposed to monitor a patient's level of consciousness by means of a device capable of detecting and analyzing cerebral activity, in an attempt to avoid awareness during surgery; however, the equipment required for such monitoring is complex in operation and costly to manufacture. It has also been proposed to use automatic equipment to monitor intra-cuff pressure in a high-volume, low-pressure cuff associated with an endotracheal tube (EDT). And it has been reported that such an EDT device is able to measure and regulate intra-cuff pressure, to a tolerance of ±3-mm mercury.

We have observed that muscle tension (tone) in the lower throat (hypopharynx) bears a relationship to the patient's apparent response to painful stimuli; thus, it is possible to gain information on the patient's anaesthetic depth by monitoring muscle tone in the hypopharynx. And we have found that very small changes in that muscle tone are reflected through the LMA cuff and are further reflected through the shared air volume and that such pressure feedback readings can be utilized to both automatically adjust the inflation pressure of the LMA cuff and also to detect changes in the muscle tone in the hypopharynx. Of course, the detection of such changes is most preferably made without causing patient duress, and to such end it has been observed that it is most beneficial to inflate the cuff to pressures not much higher than 60-cm H2O; for example, 50-cm H2O, and generally in the range 25-cm H2O to 100-cm H2O. The acceptability of utilizing pressures above 60-cm H2O has been observed to cause patient throat irritation, especially in procedures of longer duration, and may risk damage to such tissue.

BRIEF STATEMENT OF THE INVENTION

The present invention has as its overall object to provide apparatus which is capable (a) of monitoring with fine sensitivity, for example 0.0625-cm H2O, the pressure within the cuff of an LMA device that has been properly installed within a patient's airway; and (b) of maintaining a preset inflation pressure within narrow tolerances, for example ±0.5-cm H2O.

It is also an object of the invention to provide apparatus which can be pre-programmed to recognize a variety of different patterns of pressure variation within the cuff of the LMA device and if necessary, to produce an appropriate range of different warnings to the operator in response to those patterns, and to be responsive to anomalous operating conditions threatening the integrity of the LMA device.

It is a specific object to provide monitoring apparatus of the character indicated, wherein, for the case of a patient who has been anaesthetized for surgery, the monitoring of LMA inflation pressure in the course of the surgery can include such automated analysis of LMA inflation pressure variation as to warn the operator that the patient has just exhibited an anomaly indicative of an incipient stage of awakening, thereby alerting the anaesthetist or anaesthesiologist (which are terms hereinafter used interchangeably) that the patient is in immediate need of further anaesthetic.

A further object is to provide apparatus which meets the foregoing objects, is relatively inexpensive to manufacture, is straightforward to set-up, and is reliable to operate and maintain.

A still further object is to achieve the foregoing pressure regulation without resort to utilization of some other form of system whose components would introduce an additional time constant or hysteresis effect on pressure monitoring functionality; such as would be caused by an accumulator-type system that is reliant upon a pumped or otherwise elevated pressure reservoir to replenish device operating pressure.

The invention seeks also to provide a method for maintaining a predetermined pressure in an LMA device and a method for monitoring pressure changes within the LMA device to detect changes in the patient's condition and to control the administration of anaesthetic and/or muscle relaxant.

A preferred embodiment of the invention meets the foregoing objects using apparatus for automatically controlling pressure in a laryngeal-mask airway device that has been installed in a patient, wherein the LMA device includes means that is inflatable to a predetermined level of pressure to establish sealed communication between the interior of the device and the patient's laryngeal inlet, said apparatus comprising:

(a) syringe means having a piston displaceable in an elongate cylinder with an outlet connection for supply of inflation air to the inflatable means;

(b) reversibly operable drive means for reversibly displacing the piston relative to the cylinder, thereby selectively displacing air to or from the inflatable means;

(c) control means including (i) pressure-responsive means connected for response to instantaneous pressure at the outlet connection, (ii) adjustable means for selecting a set-point value of inflation pressure, (iii) comparator means connected for response to a selected set-point value, for providing an electrical-output signal representative of the difference between instantaneous pressure and the selected set-point value; and

(d) means connecting the electrical-output signal for operation of the drive means to displace the piston relative to the cylinder in the directional polarity to reduce to zero or near-zero the electrical-output signal provided by the comparator means.

Preferably, the reversibly operable drive means comprises an electric motor coupled for reversible drive of a lead-screw and nut means threaded to the lead screw, the nut means being longitudinally guided and keyed against rotation and connected for direct longitudinal displacement of the piston in the cylinder.

The preferred electric motor is a stepper motor driven in the open loop mode and which operates without slip or hysteresis lag/error. The direction and speed of the motor rotation are dependent upon the sequence and frequency of the phase of applied excitation.

More specifically, the reversibly operable drive means comprises such a stepping motor, in which the pressure-responsive means produces a first digital-signal output, in which the set-point value is in the form of a second digital-signal output, and in which the comparator means includes a microprocessor programmed to supply digital-control signals for operation of the motor.

Advantageously, a first normally closed solenoid valve is connected to the outlet connection of the syringe means for interposition between the outlet connection and the inflatable means, the solenoid of the valve having electrical connection to the control means whereby to actuate the valve to open condition for at least the time duration of the electrical-output signal and as long as the electrical-output signal is other than zero. A second normally closed solenoid valve is connected to the outlet connection of the syringe means; when actuated to open condition, this second valve provides syringe access to ambient air, for adding to or dumping system air, while the first solenoid valve is in closed condition.

Preferably, the cylinder has a ported but otherwise closed longitudinal end; and each of the two normally closed solenoid valves is connected to serve the ported end of the cylinder. The first normally closed solenoid valve is also connected to the inflatable means of the LMA and is actuable to interchange air between the inflatable means and the cylinder pursuant to the direction of displacement of the piston; and the second normally closed solenoid valve is actuable, as described above, to admit ambient air to the cylinder or to expel air from the cylinder, depending upon the direction of displacement of the piston. First limit-switch means produces an electrical signal for a sensed condition of piston advance into a predetermined limiting proximity to the closed end, and means including a microprocessor is responsive to the signal of sensed piston proximity, the microprocessor being programmed (i) to foreclose operation of the drive means and to return the first solenoid valve to its normally closed position, then (ii) to actuate the second solenoid valve to open condition while operating the drive means for a predetermined stroke in reverse, thus inducing a fresh charge of ambient air into the cylinder pursuant to the predetermined stroke in reverse, and (iii) deactivating the second solenoid valve and enabling the comparator means to reestablish the set-point value of pressure within the cylinder before reactivating the first solenoid valve and returning the comparator means to its function of regulating LMA-inflation pressure to its set-point value.

In a further microprocessor-controlled feature of the currently preferred system, as for a patient who has been anaesthetized and is undergoing surgery, mask-inflation pressure is continuously monitored. The instantaneously observed mask-inflation pressure is monitored for possible traverse of predetermined upper and/or lower threshold limits of "normal" regulation; and, upon observed-pressure traverse of one of these limits, a first alarm signal is issued with an audible warning, it being interpreted that, even though still asleep and under sedation, the patient has involuntarily betrayed an indication of hypopharynx/ larynx muscle contraction, with accompanying transient local compression of the patient's inflated LMA. Further automated monitoring is concurrently performed to determine whether any rate-related conditions occur, beyond a predetermined magnitude of an evaluated criterion. Such rate-related occurrences are further described below and are determined by continuous review of analyses performed on a gated sequence of several successive readings that are stored within the system; and the output of such analyses is continually displayed at the system monitor. This rate-related analysis of observed inflation pressure provides further indication of the patient's incipient and prospective awakening process and provides verification of first alarm, further alerting the anaesthesiologist with visual warning to "check anaesthesia".

BRIEF DESCRIPTION OF THE DRAWINGS

Apparatus and methods of the present invention will be described in greater detail by way of example and with reference to the accompanying drawings, in which:

Fig. 1 is an illustration of a control/monitor system of the invention, coupled to an LMA device installed in a patient;

Fig. 1A displays a first of two typical readouts of a percent-awakening feature, which may comprise a portion or all of a display screen;

Fig. 1B is a similar display for a second and subsequent readout of the percent-awakening feature;

Fig. 2 is a diagram of mechanical components of **Fig. 1**, with schematic indication of motor-control components;

Fig. 3 comprises separate sheets labeled **Fig. 3 (Part A)** and **Fig. 3 (Part B)**, and is a more schematic diagram of control means including a comparator component and motor-control circuit for the system of **Fig. 2**, wherein measured pressure is evaluated against a set-point **SP** for determining drive for an air-displacing piston and is further evaluated against thresholds for determining status of pain-stimulus alarms; the phantom line 3A of **Fig. 3 (Part A)**, and the phantom line 3B of **Fig. 3 (Part B)** represent one and the same plane at which **Fig. 3 (Parts 3A / 3B)** are connected to complete **Fig. 3**;

Fig. 4 is a schematic of means by which the system can transfer between start-up, centering, and reset circuitry;

Fig. 5 is a graphical display of system-observed pressure variations as a function of time in the seal cuff of an LMA that is installed in a patient who has been anaesthetized and is undergoing surgery, but has, as yet, had no pain stimulus;

Fig. 5A is a graphical display as in **Fig. 5**, just before and following display of system response to an illustrative anomaly that reflects a pain stimulus;

Fig. 6A and **Fig. 6C** are tables detailing typical calculations performed on sampled test data, comparing these values to set-point, and performing rate-related alarm calculation for each sample;

Fig. 6B and **Fig. 6D** are graphical representations of the values presented on **Fig. 6A** and **Fig. 6C**; and

Fig. 7 is a display of observed empirical data obtained during the awakening sequence of a patient; such data providing an example of a pain-stimulus response that is revealed by analysis of the monitoring function of the system.

DETAILED DESCRIPTION

A. Mechanical Construction and Operation

In **Fig. 1**, the monitoring system or device of **Fig. 2** is shown at **10** with various control buttons including a system start/stop button **52**, a "regulation" start/stop button **53**, an alarm-reset button **54**, an "ENTER" button **55**, and a rotary knob **56** for selection, *inter alia*, of set-point or threshold.

The monitoring system **10** has an outlet connection to the flexible inflation/deflation air-supply line **11** of an LMA device **12** installed in a patient **13**. The LMA device **12** is seen to comprise an airway tube **14** with proximal-end means **15** for external accommodation of ventilating or anaesthetizing supply to the patient's lungs *via* mask structure **16** having a backing plate **17** connected at **18** to the distal end of tube **14**, the backing plate being peripherally surrounded by an inflatable/deflatable ring or cuff **19** of resiliently flexible material; cuff **19** is shown in inflated condition, in peripherally sealed relation to body structure surrounding the patient's laryngeal inlet **20**, and in distally located relation to the patient's aesophageal inlet **21** (the hypopharynx). Internal structure of the mask will be understood to include known means (not shown) to prevent the patient's epiglottis **22** from interfering with air or anaesthetizing flow through the mask, in either direction, between tube **14** and the patient's laryngeal inlet **20**.

Conventionally, the inflatable/deflatable ring or cuff **19** of an LMA device is operated manually by a hand-held syringe (not shown) that is detachably connected to check-valve means **11A** forming an outer end of line **11** of the LMA; when the syringe is detached, the check-valve means **11A** is operative to retain the currently inflated or deflated state of the LMA. By experience, the anaesthetist will know roughly to what pressure the cuff can safely be inflated once the LMA has been properly installed in the patient. Although the control system can be utilized to inflate the cuff after it is installed in the patient, especially with the smaller cuff sizes, the above described manual procedure of inflation is recommended prior to connecting the LMA inflation/ deflation line **11** to the control system of **Fig. 2**.

In **Fig. 2**, an air-control port **11'** will be understood to include suitable means for detachable connection to the inflation/deflation air line **11** of **Fig. 1**; and an elongate flexible connection or extension line **11B** has (i) a system-connector end (not shown) that is detachably connected to control port **11'**, and (ii) an LMA-connector end that is compatibly connected to so coact with the connector end of the check-valve means **11A** as to maintain lines **11/11B** as a continuously open passage of system communication with inflatable means **19** of the LMA. Air-displacement means comprises syringe means in the form of a solid body **25** of low-friction material such as PTFE (Teflon) with a cylindrical bore **26** having an open (or tail) end for coaction with piston means **27**. Body **25** is fixed to a frame member **28** and extends longitudinally to a closed (or head) end having a port connection **29** to a direct line to the LMA inflation/deflation connection means **11'**; in this direct line, a first normally closed solenoid valve **V1** must be actuated to open condition if inflation air is to pass in either direction between cylinder **26** and the inflatable/deflatable means **19** of the LMA.

Piston **27** is rigidly mounted to or formed with the head end of a longitudinal rod **30**, the tail end of which is clamped to a slide block **31**. Block **31** establishes a rigid lateral-offset arm for longitudinally stabilized guidance at **32** and for reversibly driven longitudinal displacement by frame-based electrical stepper motor means **33** and its lead-screw output shaft **34**; shaft **34** has threaded engagement to a nut-like bore **34'** in the rigid lateral-offset arm of slide block **31**, and preferably the threaded bore **34'** is formed in a body of PTFE that is secured to slide block **31**. The guide means **32** will be understood to be a schematic designation for a commercial longitudinal "linear-bearing" assembly (widely known and available under the name or mark "ROLLON") wherein an elongate first raceway element is fixed to a frame member, wherein an elongate second raceway element is fixed to the slide block **31**, and wherein antifriction elements, such as bearing balls, ride and space the raceways of the respective raceway elements. The described arrangement of longitudinal support and guidance afforded by means **32** will be seen as establishing precise longitudinal displaceability of piston **27** along the central longitudinal axis of the cylindrical bore **26**, with block **31** and piston **27** effectively keyed against rotation about the lead screw.

Motor means **33** is of a stepping variety wherein a precise directional control via variance of the relative excitation of each of four input terminals of the motor. The amount of shaft **34** rotation (and thus of piston **27** displacement) is controlled by motor controller and driver means **47**, as shown in **Fig. 2**.

Legends in **Fig. 2** indicate an overall length **L** of piston **27** travel in bore **26**, for purposes of delivering inflation air from bore **26** to the inflatable/deflatable ring or cuff **19** of the LMA, as long as solenoid valve **V1** remains actuated to open condition; this same length can also be available for a retraction stroke of piston **27**, wherein a controlled quantity of inflation air may be extracted from cuff **16**. Fixedly mounted limit switches **LS1** and **LS2** are schematically indicated by arrow marks in **Fig. 2**, to suggest a stop and/or reversing device at each of the longitudinal limits of the overall length **L** of piston travel. However, as shown in **Fig. 2**, piston **27** is at offset **ΔL** outside of the cylindrical bore, wherein the arrow designated **LSO** identifies the point at which a coacting lug or other switch-actuating device **37** carried by piston rod **30** coacts with limit switch **LSO** to electrically or otherwise signal achievement of the piston-retracted position shown, with concomitant termination of drive pulses from driver circuit in **Fig. 3**; suitably and preferably, each of the limit switches is an optical device, relying on the lug or other actuating device **37** to be opaque and therefore able to cut or interrupt a light beam, from a source to a photocell, at each of the respective locations at which limit switch action is to occur.

As further shown in **Fig. 2**, the head end of piston rod **30** has a radial flange formation **38**, circumferentially shrouded by a resilient cap **39**, having an undercut bore which readily snaps into resiliently retained engagement to the flange formation **38**, as when servicing the apparatus by replacing a used cap **39** with a new cap **39**.

Some pressure-regulating operations can have the effect of causing interference with the sensing of pressure changes reflecting patient muscle reflex. The system of the invention has been designed to minimize such interference through its design concept as an essentially closed-volume system, wherein adjustments for cuff **19** pressure deviation are made by increments of displacement within a shared volume of air, as between (i) the volume ahead of the piston **26** and within the head end of the cylinder and (ii) the volume in the cuff **19**. This is superior to systems that regulate pressure by using an accumulator or reservoir of elevated pressure to compensate for cuff pressure changes either by introducing air from such an accumulator or by voiding air to atmosphere.

The inherent increase in system stability resulting from use of the shared-volume concept that is utilized by the system of the invention allows a high degree of accuracy without associated system hunting or over-adjustment. Specifically, approximately 0.0005 ml (0.5 micro-liters) of air is moved with each step taken by stepper motor **33**. Such performance is presently not available for a pressurized accumulator-type system.

Further elements of the apparatus of **Fig. 2** comprise first **P1** and second **P2** pressure-monitoring transducers. These pressure transducers, which indicate the overall pressure in the device, are connected to redundantly monitor air pressure in the line between cylinder-outlet port **29** and the normally closed first solenoid valve **V1**.

A second normally closed solenoid valve **V2** is shown connected to the air line between cylinder port **29** and the first solenoid valve **V1**. When actuated to open condition, valve **V2** establishes a path from its open-air end **44** to the air line from cylinder port **29** to the first solenoid valve, so that, with valve **V1** in its closed unactuated condition and with valve **V2** actuated to its open condition, a right-to-left displacement of piston **27** in cylindrical bore **26** will induce an inflow of fresh (ambient) air into the described system. Similarly, with the two valves **V1** and **V2** in the same condition (of **V2** actuated and of **V1** in its normally closed condition), a left-to-right displacement of piston **27** in bore **26** will discharge excess air or gas from the system.

Also, and analogously, with valve **V2** in its normally closed condition and with valve **V1** actuated to its open condition, a right-to-left displacement of piston **27** will draw inflation air from (and thus deflate) means **19** of the LMA. And for the same conditions of valve **V2** unactuated and of valve **V1** actuated, a left-to-right displacement of piston **27** will supply inflation air to means **19** of the LMA.

Control signals necessary for actuation of valves **V1** and **V2** are provided by separate outputs that are derived from basic program-sequencing signals from a separate microprocessor means of a controller **60** for start-up, centering, and reset.

A.1. <u>System Start-Up</u>

For purposes of system start-up and centering operations, the control circuit of **Fig. 3** is bypassed and the inputs to stepper motor controller and driver **47** are controlled by the controller **60** for start-up, centering, and reset. As shown in **Fig. 4**, the bypass of the **Fig. 3** control circuit is accomplished by the operation of two single-pole, two-position switches **42**. Such operation of switches **42** will occur when the unit is first powered up, at which point a start-up sequence is initiated. The operation of stepper motor **33** is controlled during start-up sequence by controller (**60**) for start-up, centering, and reset.

Before proceeding with illustrative description of automated operation of the regulating system of **Figs. 1** and **2**, it is noted that for practical purposes, the system must compatibly operate with suitably sized LMA's for patients of all ages, requiring ring **19** inflation volumes which will differ by as much as 10:1 between extremes. The sizes currently available for the anaesthetist's selection are as follows:

Size 1 (small infant), 4cc maximum inflation volume.

Size 1.5 (larger infant), 6cc maximum inflation volume.

Size 2.0 (small child), 10cc maximum inflation volume.

Size 2.5 (larger child), 14cc maximum inflation volume.

Size 3.0 (small adult), 20cc maximum inflation volume.

Size 4.0 (average adult), 30cc maximum inflation volume.

Size 5.0 (large adult), 40cc maximum inflation volume.

It is currently preferred to design the displacement-volumetric capacity of the syringe bore **26** to be substantially 20 cc, between **LS1** and **LS2** operations at the respective extremes of piston displacement **L** in bore **26**; for a bore **26** diameter of 24 mm, the displacement-volumetric capacity of 20 cc is realized by a full-stroke displacement **L** of about 45 mm, which can be taken as the illustratively useful displacement range of the system. Further illustratively, for a stepping motor **33** designed to require 1600 pulsed steps for a single revolution of its lead-screw **34**, and for a lead-screw pitch (*i.e.*, advance per turn) of 2 mm, the useful range **L** of piston **27** displacement involves 36,000 discretely pulsed step increments; for initial set-up purposes, a recommended "fast" repetition rate of pulsed steps at 5,000 Hz is to be applied to produce a piston-displacement speed of 6.25 mm/sec. For normal pressure-regulating displacements, a recommended "slow" repetition rate of pulsed steps at 500 Hz is to be applied to produce a piston-displacement speed of 0.625 mm/sec. It is explained below that any automatic pressure-regulating correction is preferably achieved by an increment of piston displacement, wherein the increment begins from the mid-point of the useful range **L**, so that the indicated regulating range of motor displacement is normally accomplished within the scope of 18,000 pulses to motor **33**, thus enabling a volume displacement of at least 10 cc, in the LMA-inflating direction or in the LMA-deflating direction, as needed. For automated regulation of LMA inflation to set-point pressure, this range limitation is found to serve any of the above-noted LMA sizes, even though the range of inflation volumes is about 10:1.

It has been recommended above that the system of **Figs. 1** and **2** be connected (at **11'**) to the inflatable means **19** of the LMA only after having followed the conventional procedure of using a hand-held syringe (not shown) to evacuate means **19** for purposes of LMA insertion in a patient, and for then using the same syringe to effect an inflation which the operator knows from experience will establish a properly located seal of means **19** around the laryngeal inlet, and with distally contacting engagement with the hypopharynx.

The preferred method of initially inflating LMA ring **19** is for the anaesthetist to use syringe means. Whether or not the LMA inflation ring **19** is inflated manually, the system of **Figs. 1, 2** and **3** is adapted to quickly assume pressure-monitoring control of inflation ring **19** to the predetermined set point, which will be understood to present a desired pressure set-point value **SP** (*e.g.*, 50-cm H2O) as part of the display **49**. Although the LMA control system **10** is capable of performing the initial task of cuff inflation, such initial inflation by the system **10** may be practical only for cuffs of smaller volume capacity and is not presently preferred.

Thus, with pressure threshold set-point **SP** selected and established for the system of **Figs. 2** and **3**, programmed operation will begin with the controller **60** (for start-up, centering, and reset) controlling the initial start-up sequence. The controller **60**, as shown in **Fig. 4**, contains an algorithm that actuates valve **V2** to open condition, leaving valve **V1** in its unactuated (and therefore in its normally-closed) condition. Pulses are then sent at high speed (5,000 Hz) *via* stepper motor controller and driver **47**, operating motor **33** to displace at high speed piston **27** from its retracted position, which is determined by lug **37** coaction with limit switch **LSO**. Piston **27** rapidly traverses the full range (**L**) of piston **27** travel in bore **26** in left-to-right motion. In the course of this traverse, lug **37** will actuate limit switch **LS1**, thereby initiating in the stepper motor controller and driver **47** a count of number of pulses that are required to drive the piston as a function of displacement **L**. The count is terminated only when lug **37** actuates limit switch **LS2**, at which point the full count is entered into memory of controller **60**, and an automatic divide-by-two operation is effected, with its half-count value entered into memory of the controller **60** and also entered into memory of the stepper motor controller and driver **47**. Thereafter the stepper motor controller and driver **47** will track each subsequent command that operates motor **33** to independently maintain an awareness of piston **27** position.

A signal is then sent by the controller **60** for travel to start in the opposite direction at the same high rate of speed until a pulse count is reached indicative that piston **27** has reached its mid-position (or "**L/2**"). Valve **V2** is then deactivated, returning it to its normally-closed condition.

Both switches **42** in **Fig. 4** then simultaneously transfer from the first ("1") position to the second ("2") position, thereby allowing a fuzzy-logic controller **46**, shown in **Fig. 3**, to assume control of motor **33**. The fuzzy-logic controller **46** will operate in accordance with logic rules set forth below in **Table 1**, providing the signal necessary for piston **27** to continue its travel in the left-to-right direction until pressure generated at the head end of the cylinder **26** equals a preprogrammed check-point pressure, typically 20-cm H2O; and once such value has been attained, for reasons explained in the following section, piston **27** will be further actuated to continue its travel until the set-point value **SP** has been attained. The controller **60** will then actuate valve **V1**, transferring **V1** to open condition.

Should the controller **60** (for start-up, centering, and reset) fail to receive indication that the preprogrammed check-point pressure has been attained within a predetermined number of stepper motor (33) steps (*e.g.*, the preprogrammed check-point pressure to be attained prior to travel of the number of steps required for piston **27** to traverse one-eighth (⅛) of displacement **L**), an audible and visual alarm will issue and the system will prohibit automatic system operation.

A.2 Failsafe mode

A failsafe mode may be triggered during the course of regular system operation upon substantial deviation between the redundant pressure sensors. The pressure is redundantly sensed by pressure transducers **P1** and **P2**, from which independently sensed pressure readings are continuously compared by a comparator means "A" **40**. A hardware-error **HW** alarm will be generated when a difference other than substantially zero is detected between **P1** and **P2**. This hardware-error alarm is issued in the form an audible and visual indication, alerting the anaesthesiologist to assume manual inflation control of the LMA. Then, a short period of time after issuing such hardware-error alarm, comparator means "A" **40** will go to failsafe mode, closing **V1** and **V2** in order to maintain the pressure within the LMA cuff.

B. Normal System Control

Fuzzy-controller operation is described by the logic rules set forth below in **Table 1**. The first two columns in **Table 1** reflect the previous pressure and the current pressure, each as compared to **SP**. As noted in **Fig. 3B**, the delay time between the first and second columns is one-half (½) second. The last column in **Table 1** reflects the command that will typically be sent by the fuzzy-logic controller **46** to motor controller **47**. Because during normal operation the stepper motor **33** operates only at slow speed, the fuzzy command is sent in terms of direction and number **(N)** of steps. The described pressure-regulating process that is conducted by the fuzzy-logic controller preferably performs its task within a range of operation defined by a deadband of 0.5-cm H2O on each side of the set-point **SP**.

Table 1

Operation of Fuzzy Logic Controller **46**

Previous Actual Pressure in relation to Set Point	Current Actual Pressure in relation to Set Point	Decision in Steps (N) and Direction
High	High	High number of steps, reverse
Medium	High	High number of steps, reverse
High	Medium	Low number of steps, reverse
Medium	Medium	Minimal number of steps, bi-directional
Low	Medium	Low number of steps, forward
Low	Low	High number of steps, forward
Medium	Low	High number of steps, forward

C. Typical Waveform for an Anaesthetized Patient

Fig. 5 illustrates a respiratory waveform which the system of the invention has used both to regulate pressure of the LMA cuff **19** and to monitor the LMA-inflation pressure. The patient in this example is under surgery and is being mechanically ventilated, *i.e.*, the patient's ventilation is the result of positive pressure being exerted through airway tube **14**, also referred to as intermittent positive-pressure ventilation, or "IPPV". **Fig. 5** depicts the ability of the device of the invention to monitor oscillations (fluctuations) about the set-point **SP** (50-cm H2O in this example), wherein such oscillations occur at a rate of approximately twelve cycles per minute, which is typical of the respiratory cycle of a "normal" anaesthetized adult patient.

It has been discovered that such respiratory flow, through airway tube **14** , whether spontaneous or by IPPV, will have the effect of causing the LMA cuff **19** to undergo regular cycles of compression/expansion. One of the objects of the system of the invention is to measure the magnitude of both the compression/expansion cycles as well as to detect deviations from such compression/expansion cycles as can be determined to indicate pain stimuli. Although there is an overall expansion of the **Fig. 5** signal envelope (as such is shown in **Fig. 5** and which will be further explained below in the section on autoscaling), there are not as of yet any indicia of pain stimuli in **Fig. 5**. **Fig. 5A** provides an example of the patient experiencing a pain stimulus, which the system of the invention will detect and report *via* alarm procedures that are the subject of discussion below.

The graph of **Fig. 5A** is illustrative of competing forces at play, once disturbed by reaction to a pain stimulus of the character indicated. First of course, one is reminded that the system of the invention will have been in its normal "regulating" mode, doing what it can, based on its repeated sampling (at 0.5-second intervals) of measured pressure (*e.g.*, **P1**) in relation to the set point **SP** and using this reading to determine and make the proper displacement of piston **27**. The pattern of neuromuscular-derived pressure variations which follow a pain stimulus, and piston displacements that will be called for and may not be within the capacity of described mechanism to track, can therefore create a disturbed pattern of measured pressures while the regulating mode is attempting to reestablish itself. Still further, the normal regulating mode and the patient's neuromuscular system will be attempting to adapt to changed and changing conditions, as may result from the patient's neuromuscular response to a deepening ("rescuing") further dose of anaesthesia.

D. Monitoring Function

Figs. 3, 5, and **5A**, and the charts and tables **Fig. 6A, 6B, 6C,** and **6D**, serve for illustration of two automatic techniques whereby the device of **Figs. 1, 2,** and **3** can alert the anaesthetist that, during the course of a surgical operation on an anaesthetized patient, the patient has given an early neuromuscular indication of a pain stimulus which the patient's current anaesthetized level has been unable to block, even though the patient is still sufficiently sedated to be unconscious or otherwise unaware of the pain stimulus. Such neuromuscular indication demonstrates to the attending anaesthetist that the patient is contracting muscles of his larynx and hypopharynx--a phenomenon indicative of an incipient stage of the patient's awakening process--with potentially serious consequences if the surgical procedure has not yet been completed.

Although it is known that patients under the effect of a general anaesthesia become insensitive to pain stimulus, such sensitivity has been discovered to be particularly active and observable at muscle systems surrounding the laryngeal inlet and the hypopharynx area. It has been further discovered that such activity of these muscle systems will vary with the depth of anaesthesia and can be observed by pressure fluctuations in an inflated LMA cuff **19** having resiliently loaded continuous contact with such muscle systems. Specifically, anomalous pressure readings in the output of pressure comparator "A" **40** are recognized by comparators "B" **57**, "C" **58**, and "D" **59** in **Fig. 3** to develop output alarms **A1** and **A2**. The inflated ring or cuff **19** of the installed LMA is thus the means of early detection of a localized neuromuscular response, which is deducible from a sudden reaction of the regulating function of the described system, as the same is seen to occur in the disturbed and irregular pattern of pressure excursions in **Fig. 5A**, wherein bracketing and legend identify a period of pain stimulus due to an event occurring during a surgical procedure.

Fig. 7 displays empirical values of the varying pressure fluctuations that were observed to occur as the anaesthetist intentionally allowed the patient to partially revive from the depths of anaesthesia, it being understood that a chart similar to **Fig. 7** was available in real time on display **49** during the course of the surgical procedure. The pressure changes are displayed on the ordinate in cm H2O, with the set-point **SP** having been selected at 60-cm H2O. **Fig. 7** displays events that transpired toward the conclusion of a surgical procedure in which the patient, "Patient 5", was anaesthetized with a continuous feed of propofol, a common and popular anaesthetic.

Three specific time periods are recognizable in **Fig. 7**, and each of these intervals corresponds to the initiation of a variance in the amount of anaesthetic administered to Patient 5. In the first of these periods, beginning at time 68-minutes, the continuous administration of propofol was stopped. And in an ensuing remainder of the first period, a significant increase in activity of muscles in the larynx/pharynx area is readily observable in the region contacted by the LMA cuff **19**.

Correlation of increased muscle activity (in the larynx/pharynx region) to the patient's depth of anaesthesia has been discovered to be of significant benefit in maintaining proper anaesthesia levels during the course of surgical and other proceedings. Use of the LMA device and monitoring apparatus provides means by which such observations can reliably be made with the additional benefit of not subjecting the patient to further intrusive apparatus.

During the second period marked in **Fig. 7**, the beginning of which occurred at approximate time 72-minutes, the anaesthetist restarts the administration of propofol. The third period in **Fig. 7**, starts at approximate time 73-minutes, and identifies when the administration of propofol was again stopped, and the patient was allowed to fully awaken. Note that there are no further readings after approximate time 82-minutes, because the LMA was at that time removed from the patient's laryngeal area.

The events displayed in **Fig. 7** provide clear evidence that the monitoring system of the invention functions at a level of sensitivity permitting detection of muscular activity indicative of the awakening sequence.

D.1 <u>Automated Alarms</u>

Two techniques recommended for automatic interpretation of the anomaly described in **Fig. 5A** are further described below. These alarms can be monitored by the anaesthetist for immediate or early recognition of the pressure anomaly that has been observed as a symptom caused by an early incipient stage of the patient's awakening process.

Both techniques rely upon the establishment of fluctuation boundaries (thresholds) on each side of the normal respiration waveform and the comparison of LMA (ring **19**) pressure to such limits; these are shown as upper and lower thresholds **E1** and **E2** in **Figs. 5** and **5A** and are referred to as the "check anaesthesia alarm window". As shown in **Fig. 3**, **E1** and **E2** are the values automatically compared to each pressure signal fluctuation for determination of the anaesthesia-level alarms, **A1** and **A2**. The attending anaesthetist is able to individually select, i.e., to vary **E1** and **E2** via monitoring device **10**. **A1** is an instantaneous-type alarm, triggered whenever the respiration waveform deviates above or below the "check anaesthesia" alarm window that is framed by **E1** and **E2**. The initial warning alarm **A1** is triggered by any single deviation from the "check anaesthesia" alarm window. The **A1** alarm will be presented to the anaesthesiologist in audible form. Once thus warned, the anaesthetist is alerted to make an immediate corrective response, as by increasing the strength of the anaesthetic being administered to the patient.

Alarm **A2** is a rate-related alarm that is determined (i) by a window-related value **ET** (explained below) and (ii) a calculated mean ($\bar{Y}$) based on successive samples of the detected waveform of varying LMA-inflation pressure, wherein the samples are taken for each successive 0.1-second sampling interval, and are effectively integrated and stored as absolute values in a word-summing array circuit, as shown in **Fig. 3**; each of the absolute values is taken for its sampled magnitude with reference to a steady base line, conveniently the set-point value, as shown in **Figs. 6A** and **6B**. If the mean value, i.e., the sum of the most recent successive thirty-two integrated samples, divided by 32 (**61**, **Fig. 3A**), exceeds the value **ET**, as further explained below, the **A2** alarm will issue, such as "CHECK ANAESTHESIA", to the anaesthetist by a combination of visual and/or audio signals. The anaesthetist is thereby further alerted to make an immediate corrective response, as by increasing the strength of the anaesthetic which is being administered to the patient. **ET** is calculated by adding the absolute values of **E1** and **E2**, and dividing the sum thereof by a selected constant **k**, *i.e.*,

$$\mathbf{ET} = \frac{1}{\mathbf{k}} \left[|\mathbf{E1}| + |\mathbf{E2}| \right] ,$$

wherein **k** is a selected value in the range 3 to 6 (and preferably 4), it being explained that with **k** = **4**, the "divide-by-4" relationship establishes a preferred practical safety factor by means of which the "CHECK ANAESTHESIA" alarm is reliably issued even though the instantaneous-type alarm **A1** may not have issued.

As shown in **Fig. 3**, at the conclusion of each 3.2-second sampling period, the oldest sample is discharged and the latest sample is incorporated in the new calculation of mean value for the next 32-sample comparison to **ET**.

Thus, for example, the anomaly depicted in **Fig. 5A**, which is illustrative of a pain-stimulus event observed in a surgical procedure, will be seen to give rise to determinations which are major departures from the normal situation depicted in **Fig. 5**. If an initial sample traverses one of the boundaries of the alarm window, the first alarm **A1** will be triggered, and the second alarm **A2** may not immediately be triggered. However, the integration and mean-value development described above can result in a "CHECK-ANAESTHESIA" alarm **A2**, even if a threshold-traverse needed for the first alarm **A1** may not have occurred. In addition to these two alarms, the anaesthesiologist may monitor continued progression in the form of percent awakening that can be displayed as shown in **Fig. 1B**, the same being discussed below under the heading, "Display Feature".

Although the graph of **Fig. 5A** reflects interplay of various reactions, it is particularly noted that, once such reactions are detected, major transient departures from the set-point **SP** are eliminated within substantially 30 seconds by prompt administration of additional anaesthesia.

D.2. <u>Display Features</u>

The display **49** contains a window of time through which the continuously varying signal, such as that shown in **Figs.** 5, **5A**, **6B**, **6D**, and **7**, will show the latest single full minute of regulated pressure variations, passing into the window at its left-hand margin, and passing out of window viewability at the right-hand margin.

An additional method for displaying the results of the above-described integration/summation process (mean value) is shown in **Fig. 1A** and **Fig. 1B**, where these two displays in the course of time indicate a progression, from a deeper level of anaesthesia, shown in the first example **Fig. 1A**, to an incipient level approaching awakening, shown in the second example **Fig. 1B**. The display preferably consists of a bar chart that shows, as on a percent scale, the output of the successively integrated function described above. The initial value of this continually-updated display is established for each individual patient, preferably after the anaesthetized patient is positioned by the surgeon on the operating table, in readiness for surgery. The parameter equivalent to a 100% display reading will equate to the full value of **ET**, at which point the "CHECK ANAESTHESIA" alarm will issue.

Also provided for utilization by anaesthetist and/or other personnel studying a particular surgical procedure is the ability to connect separate microprocessor or other data-presentation means to a computer interface **41**, thus providing for the monitoring, recording and analysis of system indicators on separate electronic media, as when more sophisticated recording and analyses are desired.

D.3. <u>Autoscaling of Alarm Window</u>

It has been discovered that the monitoring function of the system of the invention can be made more efficient by allowing the size of the check-anaesthesia alarm window to be automatically reduced (or autoscaled), thereby providing an advantage of faster alarm threshold (*i.e.*, **E1** and **E2**) adjustment and therefore more accurate monitoring of anaesthesia level. To accomplish such autoscaling of the check-anaesthesia alarm window, both the upper and the lower peak amplitudes from at least eight consecutive waveforms are sampled, averaged, and mean values for the upper and lower peaks are determined. Two checks for validation of peak values are used; all eight upper and lower limits that are sampled must be obtained during the same two-minute sampling period, and small oscillations that may otherwise be identified as peaks can be eliminated by operator input of a preset minimum amplitude.

These upper and lower peak amplitudes define, in essence, an "envelope" that typically decreases in accordance with the patient's compliance to positive pressure ventilation (IPPV), as the patient becomes more anaesthetized. In considering the usefulness of a need to reestablish alarm thresholds in the sense of following an envelope of decreasing amplitude (or size), it must be remembered that the patient's respiratory pressure is commonly reduced as the patient becomes more compliant. Limiting the alarm thresholds (i.e., **E1** and **E2**) has been found to be an effective and desirable method for automatically reestablishing the sensitivity of the monitoring device so that pain-stimulus derivation will continue to be detected, despite a reduction in envelope size.

As a safety consideration, the preferred device will allow the autoscaling feature only to reduce, and not to automatically enlarge, the check anaesthesia alarm window. The amount by which autoscaling can vary **E1** and **E2** is fully adjustable between zero and one hundred percent, with a default value of fifty percent. It is interesting to note that such autoscaling frequently causes **E1** and **E2** to no longer be symmetrical about set-point **SP**, similar to the alarm window shown in **Fig. 6B**.

D.4. <u>Re-Centering Operation System</u>

As described above, the system of the invention will automatically compensate for leaks and gains in monitored inflation air. Because the stepper motor controller and driver **47** maintain a count of direction commands issued to the stepper motor **33**, the stepper motor driver **47** is able to and will so indicate when piston **27** has reached an end of its travel. Such indication will operate switches **42** to position "1" and trigger the initiation of a "reset" function governed by the controller **60**, for start-up, centering, and reset. Depending on the reset command sent by motor controller **47**, i.e., when an anomalous condition requires a replenishment or purge of piston air, appropriate action will be taken by the controller **60**. For example, when the reset function requires that air be added to the system, the controller **60** will (i) deactivate solenoid valve **V1**, returning it to its normally closed state; (ii) activate solenoid valve **V2** to an open condition; and (iii) send appropriate signals to stepper motor controller and driver **47**, thereby causing piston **27** to be driven by motor **33** at high speed to exhaust excess "air" (or, where appropriate, taking in additional fresh air) via port **44**. The memory of the controller **60** will have retained from the system start-up procedure described above, the number of pulses required to drive piston **27** to its or midposition **(L/2)**.

In normal monitoring and regulatory operation of the described system, there will be little call for great displacements of piston **27**. But large displacements can occur, for example, a loss of monitored inflation air may be caused by surgical-knife contact with the inflated LMA ring **19**. This condition will be observed by the system, calling for continued supply of either additional or reduced inflation air depending upon whether lug **37** coacts either with limit switch **LS1** or **LS2**, thereby indicating that piston **27** has reached the end of its travel. Such limit-switch signal will cause: (i) switches **42** to bypass the **Fig. 3** control circuit; (ii) the sending of an alerting notice to the anaesthetist, as in the form of an audible alarm, with visual display of the message, "CHECK FOR LEAKS"; and (iii) the triggering of the reset function of controller **60**, as is described above.

The above description highlights an additional advantage of the automated device in that it will, as described, replenish the volume of air in cylinder **26** within approximately 3.6 seconds, which is significantly faster than typically possible by manual operation. Despite such favorable automatic recovery time, the pressure adjustments made by the system are sufficiently discrete to allow pressure regulation of the smallest LMA cuff without causing undue pressure rebound within the small volume.

All such operations are automatic, as are the warnings or alarms that are part and parcel of assuring maintenance of set-point pressure, for as long as the circumstances may require for a given patient, or for a given LMA size that the patient is deemed to require.

Conclusion

The described device and its method of use will be seen to have achieved all stated objects, acting as a controller of LMA-cuff pressure, as a device that will monitor and correct for leaks, as a monitor of a possible pain stimulus to the patient's neuromuscular system while the patient is anaesthetized for the course of a surgical procedure, and as a monitor to prevent a patient from remaining under the effect of a muscle relaxant while not being adequately anaesthetized. In particular:

1. The device is controlled by a microprocessor unit which performs all tasks including, but not limited to, diagnostic checks, motor and valve operation and control, and pressure measurement.

2. The device includes a graphic display and control unit as well as an interface for advance monitoring and control thus permitting data evaluation with different commercial software packages.

3. The device provides instantaneous values of LMA-cuff pressure via redundant pressure sensors that are pneumatically connected to the inflation line of the LMA cuff. For safety reasons, the pressure measurement is taken by redundant transducers, of which an automatic comparison is continuously performed.

4. The device normally operates with the same volume of air, seeking maintenance of set-point pressure for LMA-cuff inflation, wherein for each sampling measurement of LMA-cuff pressure, departure from set-point value causes piston displacement in the direction to reduce to zero (or to substantially zero)

the departure of measured pressure from set-point pressure.

5. The device is so detachably connected to the inflation/deflation air line of the LMA as to permit normal LMA-patient installation procedures, without relying upon any of the automatic features of the device. As a consequence, the patient may be "prepped" for the operation by having the LMA installed, with inflated cuff, and completely checked to assure that it has been properly installed, before the patient enters the operating room, thus relying on a check valve to hold inflation pressure, prior to device-connection of the patient and the inflated-LMA cuff.

6. If, for any reason, the system is not working or is not working properly, the system will revert to a fail safe mode, with operational valves returning to their normally closed condition, thereby maintaining LMA inflated-cuff pressure.

7. In its normal regulation mode, system-pressure sampling is at every one-tenth (1/10) of a second, with ample time to accomplish evaluation against set-point pressure, and issuance of a train of pulses is for such piston displacement as will achieve a measured-pressure correction to substantially set-point pressure. Normal regulation occurs if evaluation of a pressure sample exceeds a threshold value of ± 0.5-cm H2O from an adjustable set-point value.

8. It is important to emphasize that normal operation of the described LMA system exhibits major advantages which flow from the fact that the system works with a virtually closed volume of air. An increase of measured pressure will rapidly cause displacement of a portion of the volume of air from the LMA cuff and into the volume defined between the

piston and the head end of the cylinder; and this volume of air will be returned to the LMA cuff virtually as soon as measured pressure is detected to have decreased. This sharing of the same volume of air is always true, except when, due to a leak or to some other unexpected event, the piston reaches the end of its travel, as such is tracked by position-counter operation maintained within the stepper motor controller or upon reaching of one of the limit switches, at which point the piston will be repositioned, with an air discharge or an uptake of fresh air, as the occasion may dictate, all while the LMA cuff can retain its inflation pressure.

9. Once stabilized, the described system is found to be sensitive to very small pressure variations (in the order of 1/16-cm H2O) and can be quick and precise in its response without contaminating the monitoring function with time constant or hysteresis transients. It is believed that such response is achieved because of the described stepping motor and lead-screw drive, in combination with normal regulating displacements within the virtually closed volume of air. Reliance on the virtually closed volume of air translates into involvement of only one time constant in the increasing or in the decreasing of intra-cuff pressure in the LMA.

10. As an aid to the anaesthesiologist and in the course of a surgical procedure on a patient, the described system permits several concurrently operative algorithms to process, in real time or in close to real time, the anaesthetized patient's initial, incipient and totally involuntary muscular symptoms of arousal from induced sleep and/or paralyzed state, *via* sensitive response to muscular action observed around the patient's laryngeal inlet and/or at contact with the patient's hypopharynx.

Provision is made for audibly and visually alerting the anaesthesiologist to detect approach of patient awakening, in good time to "check anaesthesia" and to institute corrective measures without patient awakening. The described system is seen to be inherently capable of adapting itself to enhanced precision of detecting loss of depth of anaesthesia as it progressively narrows the focus of its attention to a predetermined margin of safety in evaluating observed fluctuations in LMA-inflation pressure.

11. The monitoring function of the described system may be useful in detecting and providing means to guard against a circumstance in which the patient, who has been administered both an anaesthetic and a separate muscle relaxant (*e.g.*, atracurim or vecuronium), has the anaesthetic wear off while remaining immobilized due to the continuing effect of only the muscle relaxant. Such circumstance has been known to be highly unpleasant due to the patient's inability to reveal that the patient is experiencing the full effect of surgical manipulations. The LMA monitoring system may be useful as a guard against such an event, in view of the more limited effect of some muscle relaxants upon pharyngeal constrictor muscles, which the LMA cuff **19** necessarily contacts with its ability to monitor for muscle activity. Others have observed that the contraction curve of the pharyngeal constrictor muscles is unchanged during partial paralysis caused by a common muscle relaxant. *See*, Ericsson, *et al.*, *Functional Assessment of the Pharynx at Rest and during Swallowing in Partially paralyzed Humans*; Anaesthesiology, V 87, No. 5, Nov. 1997.

12. It is noted further that although the monitoring and other detecting functions of the described system are preferably in the context of LMA inflation response, the LMA context is merely

illustrative of use of a suitable inflated device within the pharyngeal cavity to respond to and produce appropriate warning of the muscle action in the region of inflated-material contact with one or more regions of muscle action.

13. And it is also noted further that preferred numerical values stated herein as 4, 8, 32, etc. are only illustrative and that they have been selected as power values of 2, in view of the preferred reliance on digital-system operation.

MONITORING AND CONTROL
FOR A
LARYNGEAL MASK AIRWAY DEVICE

WHAT IS CLAIMED IS:

1. Apparatus for automatically regulating pressure in a laryngeal-mask airway (LMA) device that has been installed in a patient, wherein said LMA includes inflatable means that is inflatable to a predetermined level of pressure to establish a seal around the patient's laryngeal inlet, said apparatus comprising:

   a. syringe means having a piston displaceable in an elongate cylinder with an outlet connection to said inflatable means for supply of inflation/deflation air;

   b. Reversibly operable drive means for reversibly displacing said piston and cylinder with respect to each other whereby to selectively displace air to or from said inflatable means;

   c. Control means including:

      (i) Pressure-responsive means connected for response to instantaneous pressure at said outlet connection,

      (ii) Adjustable means for selecting a set-point value of inflation pressure, and

      (iii) Comparator means connected for response to said set-point value and to said pressure-responsive means for providing an output representative of the polarity of an evaluated difference between instantaneous pressure and the selected set-point value; and

d. Means connecting said output for operation of said drive means to displace said piston and cylinder with respect to each other in the directional polarity to reduce to zero the output provided by said comparator means.

2. Apparatus according to claim 1, in which said cylinder has a head end having ported inflation-air connection to said LMA, thereby defining a substantially constant included volume of air between said piston and the head end of the cylinder for shared inclusion with inflation air in the inflatable means of the LMA.

3. Apparatus according to claim 1, in which said reversibly operable drive means comprises a motor coupled for reversible drive of a lead-screw, and nut means threaded to said lead screw, said nut means being longitudinally guided and keyed against rotation and connected for direct longitudinal displacement of said piston in said cylinder.

4. Apparatus according to claim 1, in which said reversibly operable drive means comprises a digitally controlled stepping motor, in which said pressure-responsive means produces a first digital-signal output, in which said set-point value is in the form of a second digital-signal output, and in which said comparator means includes a microprocessor programmed to supply digital signals for operation of said motor.

5. Apparatus according to claim 1, in which said outlet connection includes valve means operable to determine an open or a closed condition of air displaceability between said inflatable means and the head end of said cylinder.

6. Apparatus according to claim 5, in which said valve means is a first of two valves, the second of said valves having tapped connection to said outlet connection at a location between said first valve and said cylinder, said second valve being operable to determine an open or a closed condition of outlet-connection communication with ambient air.

7. Apparatus according to claim 6, in which each of said valves is a normally closed solenoid valve, said first valve having electrical connection to said control means whereby to enable pressure regulation of the inflatable means of the LMA, and said second valve having electrical connection to said control means, whereby to enable automatic discharge or induction of air in the maintenance of a substantially constant shared collective volume of air within said inflatable means and within the head end of said cylinder.

8. Apparatus according to claim 7, wherein said apparatus includes air-incrementing means to admit a predetermined quantity of ambient air into said cylinder, said air-incrementing means comprising:

limit-switch means producing an electrical signal for a sensed condition indicative of piston advance into a predetermined proximity to said head end and corresponding to a head end of allowable piston travel; and means including a microprocessor responsive to said signal of sensed piston proximity, said microprocessor being programmed in a manner

(i) to return said first solenoid valve

to its normally closed condition, and

(ii) to actuate said second solenoid valve to open condition and then operating said drive means for a predetermined stroke in reverse, thus inducing a fresh charge of ambient air into said cylinder pursuant to said predetermined stroke in reverse, and

(iii) to deactivate said second solenoid valve and enable said comparator means to reestablish the set-point value of pressure within said cylinder before reactivating said first solenoid valve and returning said comparator means to its function of regulating LMA-inflation pressure to its set-point value.

9. Apparatus according to claim 7, wherein said apparatus includes air-purging means to purge a predetermined quantity of air from said cylinder, said air-purging means comprising:

limit-switch means producing an electrical signal for a sensed condition indicative of piston advance into a predetermined proximity to a tail end of allowable piston travel; and means including a microprocessor responsive to said signal of sensed piston proximity, said microprocessor being programmed

(i) to return said first solenoid valve to its normally closed condition, and

(ii) to actuate said second solenoid valve to open condition and then operating said drive means for a predetermined stroke in reverse, thus inducing a predetermined purge of air out of said cylinder, and

(iii) deactivating said second solenoid valve and enabling said comparator means to reestablish the set-point value of pressure within said cylinder before reactivating said first solenoid valve and returning said comparator means to its function of regulating LMA-inflation pressure to its set-point value.

10. Apparatus according to claim 7, wherein head-end limit-switch means is positioned to produce an electrical signal for a sensed condition of piston advance into predetermined proximity to a head end of allowable piston travel, and wherein tail-end limit-switch means is positioned to produce an electrical signal for a sensed condition of predetermined proximity to a tail end of allowable piston travel, and wherein said control means includes microprocessor means programmed to determine (i) piston drive in the direction of approach to the head-end limit-switch and (ii) actuation of said first valve to open condition, for displacing air from the head end of said cylinder to said inflatable means; said microprocessor means being further programmed to determine (iii) piston drive in the direction of retreat from said head end, and (iv) actuation of said first valve to open condition, for a displacement of air from said inflatable means to the head end of said cylinder.

11. Apparatus according to claim 10, wherein said microprocessor means is further programmed, in the event of an advancing piston displacement which actuates the head-end limit-switch, (v) to deactivate said first valve and to activate said second valve to open condition, and (vi) to determine reversal of piston drive for a retraction of said piston and for a concomitant induction of air into the head end of said cylinder; said microprocessor being further programmed, (vii) to terminate the reversed drive of said motor and (viii) to deactivate said second valve and to actuate said first valve for a reestablished sharing of a fixed volume of air between said inflatable means and the head end of said cylinder.

12. Apparatus according to claim 11, wherein said microprocessor means is further programmed in the event of a retracting piston displacement which actuates the tail-end limit switch, (v) to deactivate said first valve and to actuate said second valve to open condition, and (vi) to determine reversal of piston drive for a new direction of advance toward the head end of said cylinder and for a concomitant predetermined purge of air from said apparatus without change of the inflated condition of said inflatable means; said microprocessor being further programmed (vii) to terminate piston advance in said new direction and (viii) to deactivate said second valve and to actuate said first valve for a reestablished sharing of a fixed volume of air between said inflatable means and the head end of said cylinder.

13. Apparatus according to claim 1, wherein said adjustable means provides for set-point value selection within the range 25-cm H20 to 100-cm H20.

14. Apparatus according to claim 1, wherein said adjustable means provides for set-point value section within the range 40-cm H20 and 70-cm H20.

15. Apparatus according to claim 14, wherein the selected set-point value is substantially 50-cm H20.

16. Apparatus according to claim 14, wherein the

selected set point value is substantially 60-cm H20.

17. Apparatus according to claim 13, wherein said apparatus has a fine sensitivity of pressure regulation in the order of 0.06-cm H20 in the monitoring of pressure within the inflatable means of the LMA.

18. Apparatus according to claim 13, wherein said apparatus has the ability to regulate within relatively narrow tolerances of the pressure within the inflatable means of the LMA.

19. Apparatus according to claim 18, wherein said relatively narrow tolerances are substantially ± 0.5-cm H20.

20. Apparatus according to claim 1, in which said apparatus is adapted for selective connection to the inflatable means of an installed LMA wherein the installed LMA is any one of a plurality of LMA sizes that are dependent upon relevant anatomical size of the patient.

21. Apparatus according to claim 20, in which the inflated volume of the inflatable means of said LMA sizes in the range of 4cc to 40cc.

22. Apparatus according to claim 1, in which the displacement-volumetric capacity of said cylinder is in the order of 20cc.

23. Apparatus according to claim 23, in which said cylinder has a bore that is approximately half the effective displaceable length of piston displaceability in said cylinder.

24. Apparatus for automatically monitoring the anaesthetized status of a patient in the course of a surgical procedure on the patient, wherein the patient has an installed LMA device which comprises an airway tube with an inflatable mask at its distal and for sealing engagement around the laryngeal inlet, with communication to the patient's lungs via the tube and through the mask, said mask having a flexible tubular inflation line accessible externally of the patient; said apparatus comprising:

(a) means including a pressure transducer detachably connected to said inflation line for producing an electrical-signal output pursuant to instantaneous LMA-inflation pressure as a function of time during the surgical procedure;

(b) pressure evaluating means including adjustable means for setting predetermined upper and lower signal limits of transducer electrical-signal output representing tolerable upper and lower threshold limits of LMA-inflation pressure fluctuation; and

(c) said pressure-evaluating means producing an alarm-signal output upon detected occurrence of an electrical signal which either exceeds the upper one of said limits or is less than the lower one of said limits.

25. Apparatus according to claim 24, further including display means for continuously displaying transducer-observed pressure as a function of time, wherein a predetermined span of time displays pressure amplitude as varying ordinate values continuously passing from one to the other limit of span of time, with the current and most recently observed pressure at said one limit, said display means further displaying, said predetermined upper and lower tolerable limits as separate. Horizontal lines able and below the display of LMA-inflation pressure, whereby after administration of anaesthetic to the patient and before commencement of surgery, a judgment may be exercised in the setting of said threshold limits, so that the limits for an alarm condition may be predetermined to indicate an alarm condition applicable essentially only to an event occurring after commencement of surgery on an anaesthetized patient.

26. Apparatus according to claim 24, further including display means for continuously displaying transducer-observed pressure as a function of time, wherein a predetermined span of time displays pressure amplitude as varying ordinate values continuously passing from one to the other limit of said span of time, with the current and most-recently observed pressure at said one limit, said display means further displaying said predetermined upper and lower tolerable limits as separate horizontal lines above and below the varying display of LMA-inflation pressure, whereby after administration of anaesthetic to the patient and before commencement of surgery, a judgment may be exercised in the setting of said threshold limits, so that the limits for an alarm condition may be predetermined to indicate an alarm condition applicable essentially only to an event occurring after commencement of surgery on an anaesthetized patient.

27. Apparatus for automatically monitoring the anaesthetized status of a patient in the course of a surgical procedure on the patient, wherein the patient has an installed LMA device which comprises an airway

tube with an inflatable mask at its distal end for sealing engagement around the laryngeal inlet, with communication to the patient's lungs via the tube and through the mask, said mask having a flexible tubular inflation line accessible externally of the patient; said apparatus comprising:

(a) means establishing a set-point pressure as a reference quantity;

(b) means including a syringe having a cylinder with a head end adapted for detachable connection to said LMA-inflation line, said cylinder having a tail end through which a piston is displaceable to change the proportion of a closed volume of air that is shared between the inflatable mask and the head end of the cylinder;

(c) means for sensing air pressure within said closed volume and for comparing the sensed pressure to said reference quantity, whereby to determine the polarity of a sensed departure from said reference quantity; and

(d) regulating means including drive means for reversibly displacing said piston in said cylinder in the direction and to the extent to cause the sensed air pressure to reduce to zero the said sensed departure.

28. Apparatus according to claim 27, wherein said apparatus includes microprocessor means programmed to establish separate upper and lower tolerable thresholds of sensed air-pressure fluctuation, and to provide an output warning of a detected occurrence of a pressure fluctuation which has traversed one of said thresholds.

29. Apparatus for automatically monitoring the anaesthetized or paralyzed status of a patient in the course of a surgical procedure on the patient, wherein the patient has an installed inflatable device having wall contact with at least a portion of the patient's hypopharynx, and wherein the inflatable device has a flexible tubular inflation line accessible externally of the patient; said apparatus comprising:

(a) means establishing a set-point pressure as a reference quantity;

(b) means including a syringe having a cylinder with a head end adapted for detachable connection to said inflation line, said cylinder having a tail end through which a piston is displaceable to change the proportion of a closed volume of air that is shared between the inflatable device and the head end of the cylinder;

(c) means for sensing air pressure within said closed volume and for comparing the sensed pressure to said reference quantity, whereby to determine the polarity of a sensed departure from said reference quantity; and

(d) regulating means including drive means for reversibly displacing said piston in said cylinder in the direction and to the extent to cause the sensed air pressure to reduce to zero the said sensed departure.

30. Apparatus according to claim 27 or claim 29, further comprising display means connected to said sensing means for establishing a continuously running display of sensed inflation pressure against time.

31. Apparatus according to claim 27 or claim 29, further comprising display means connected to said sensing means for establishing a continuously running display of sensed inflation pressure against time; and

(e) pressure-evaluating means including adjustable means for setting and lower threshold limits of sensed air-pressure fluctuation, said pressure-evaluating means providing a warning upon a detected occurrence of a pressure fluctuation outside one of said limits.

32. The method of using an LMA device to monitor the anaesthetized status of a patient in the course of a surgical procedure on the patient, wherein the LMA device comprises an airway tube with an inflatable mask at its distal end for sealing engagement around the laryngeal inlet and for establishing exclusive communication to the patient's lungs via the tube and through the mask, said mask having a flexible tubular inflation line accessible externally of the patient; said method comprising the steps of:

(a) Selecting and installing the LMA device in the patient with mask inflation to establish a sealed engagement around the patient's laryngeal inlet;

(b) Selecting and connecting a pressure-sensitive device to said inflation line, whereby to continuously monitor instantaneous inflation pressure fluctuations as a function of time during the surgical procedure;

(c) Analyzing fluctuations in sensed pressure for a period of time prior to commencement of the surgical procedure to establish a window between upper and lower pressure limits within which the observed fluctuations are contained;

(d) Commencing the surgical procedure; and

(e) Issuing a warning in response to a monitored pressure level which traverses one of said limits.

33. The method of using an LMA device to monitor the anaesthetized status of a patient in the course of a surgical procedure on the patient, wherein the LMA device comprises an airway tube with an inflatable mask at its distal end for sealing engagement around the laryngeal inlet and for establishing exclusive communication to the patient's lungs via the tube and through the mask, said mask having (i) a distal end configured for locating contact with the patient's hypopharynx and (ii) a flexible tubular inflation line accessible externally of the patient; said method comprising the steps of:

(a) Selecting and installing the LMA device in the patient with mask inflation to establish (iii) a sealed engagement around the patient's laryngeal inlet and (iv) distally locating mask engagement with the patient's hypopharynx;

(b) Selecting and connecting a pressure-sensitive device to said inflation line, whereby to continuously monitor instantaneous inflation pressure fluctuations as a function of time during the surgical procedure;

(c) Analyzing fluctuations in sensed pressure for a period of time prior to commencement of the surgical procedure to establish a window between upper and lower pressure limits within which the observed fluctuations are contained;

(d) Commencing the surgical procedure; and

(e) Issuing a warning in response to a monitored pressure level which traverses one of said limits.

34. The method of claims 32 or claim 33, wherein the window of step (c) further includes a continuously running fixed span of time in which the absolute magnitude of pressure variations within said upper and lower limits are integrated to ascertain a mean value for said span of time; and

wherein a criterion value is established as an additional limit of tolerable magnitude; and issuing an alarm upon determining that said criterion value has been reached by the ascertained mean value.

35. The method of using an LMA device to monitor the anaesthetized status of a patient in the course of a surgical procedure on the patient, wherein the LMA device comprises an airway tube with an inflatable mask at its distal end for sealing engagement around the laryngeal inlet and for establishing exclusive communication to the patient's lungs via the tube and through the mask, said mask having a flexible tubular inflation line accessible externally of the patient;

(a) Selecting and installing the LMA device in the patient with mask inflation to establish a sealed engagement around the patient's laryngeal inlet;

(b) Selecting and connecting a pressure-sensitive device to said inflation line, whereby to continuously monitor instantaneous inflation pressure as a function of time during the surgical procedure;

(c) Commencing the surgical procedure;

(d) Analyzing fluctuations in pressure for a period of time after commencement of the surgical procedure to establish a window between upper and lower pressure limits within which the observed fluctuations are contained; and

(e) Issuing a warning in response to a monitored pressure level which traverses one of said limits.

36. A method of maintaining a predetermined set-point pressure in a laryngeal-mask-airway device (LMA) that has been installed in a patient, wherein said mask includes inflatable means that has been inflated by operation of a syringe to establish a seal around the patient's laryngeal inlet, said method comprising the steps of:

a. establishing said set-point pressure as a reference quantity,

b. sensing the pressure level of the inflatable means for the polarity of possible deviation of mask-inflation pressure from said set-point pressure,

c. operatively displacing the piston of the syringe in the direction and to the extent involved to reduce to zero the possible deviation of inflation pressure with respect to set-point pressure, and

d. repeatedly iterating steps (b) and (c) throughout the course of anaesthetizing the patient during a surgical procedure.

37. The method of claim 35, wherein the use of step (e) includes actuation of a first automatic alarm operative upon a sensed instantaneous-pressure value falling outside of a range of preset alarm values.

38. The method of claim 37, wherein said preset alarm values can be manually adjusted.

39. The method of claim 35, wherein the use of step (e) includes actuation of a second automatic alarm operative upon the product of stepped integration of sensed instantaneous-pressure values exceeding a second preset threshold alarm value.

40. The method of claim 39, wherein said preset second preset threshold alarm value can be manually adjusted.

41. The method of claim 39, where each subsequent product of the stepped integration is compared to each individual anaesthetized patient's initial stepped integration and such comparison, whereby to provide an indication of attenuation of the patient's depth of anaesthesia, and such continuous display provides an additional separate indication of the incipient awakening of the anaesthetized patient which may be used to alert the anaesthetist of the need for an incremental additional supply of anaesthetic to the patient.

42. The method of using the apparatus recited in claim 1, to detect an incipient stage of premature patient awakening from anaesthetized condition, wherein the pressure sensed by the comparator means of said apparatus establishes a continuously running display of sensed inflation pressure against time.

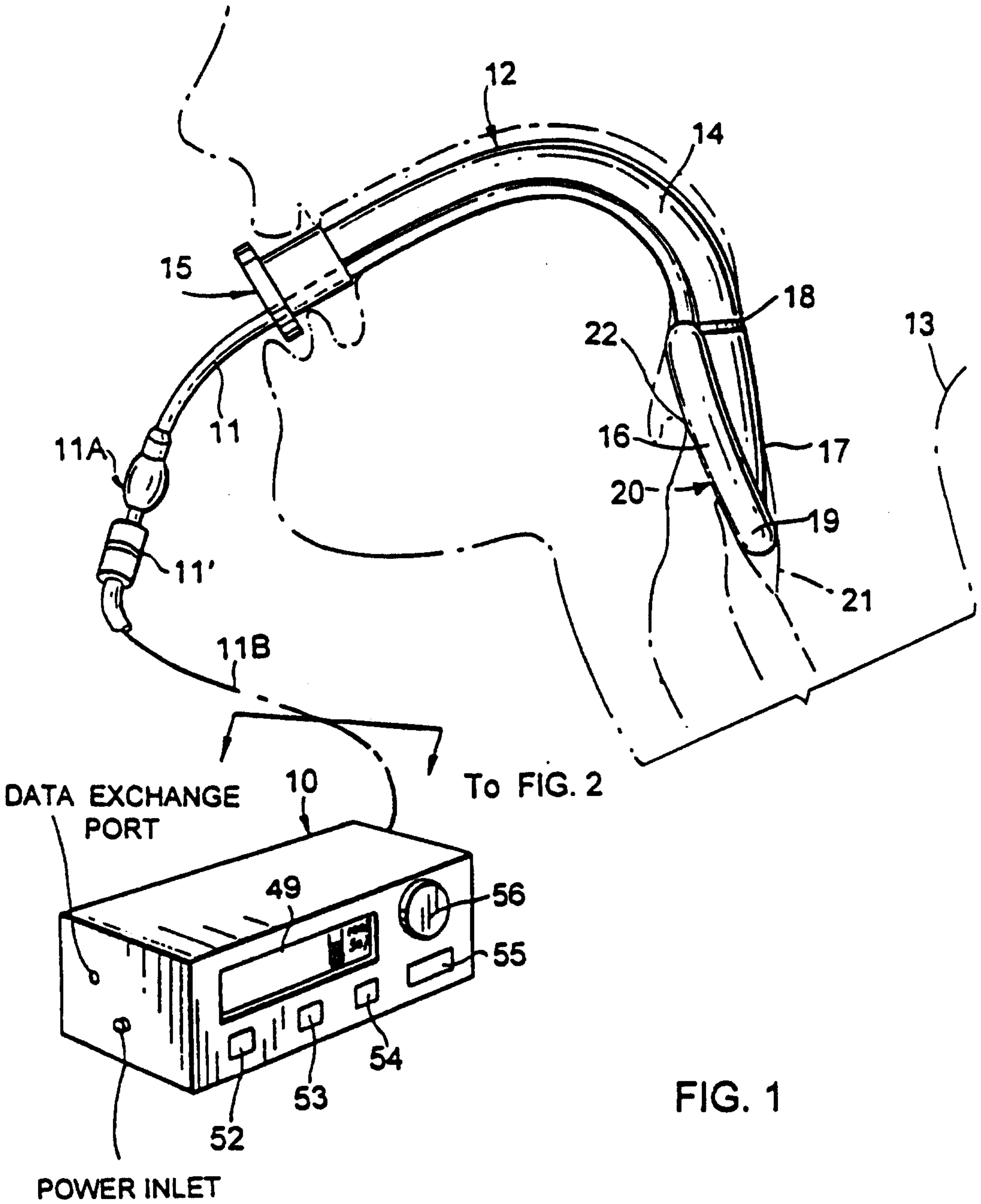
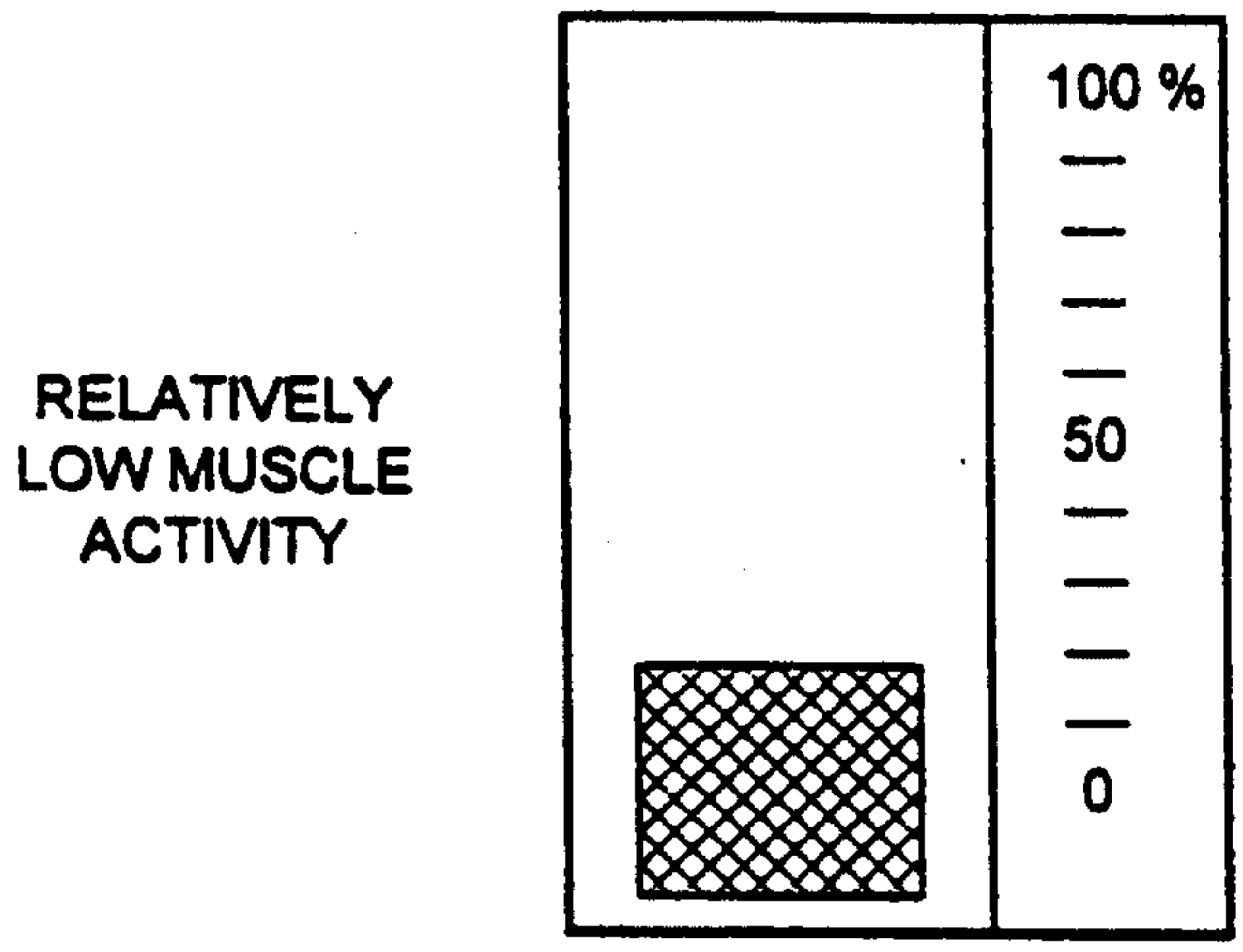

12
14
15
18
22
13
16
17
11
11A
20
19
11'
21
11B
To FIG. 2
DATA EXCHANGE PORT
10
49
56
55
52
53
54
POWER INLET

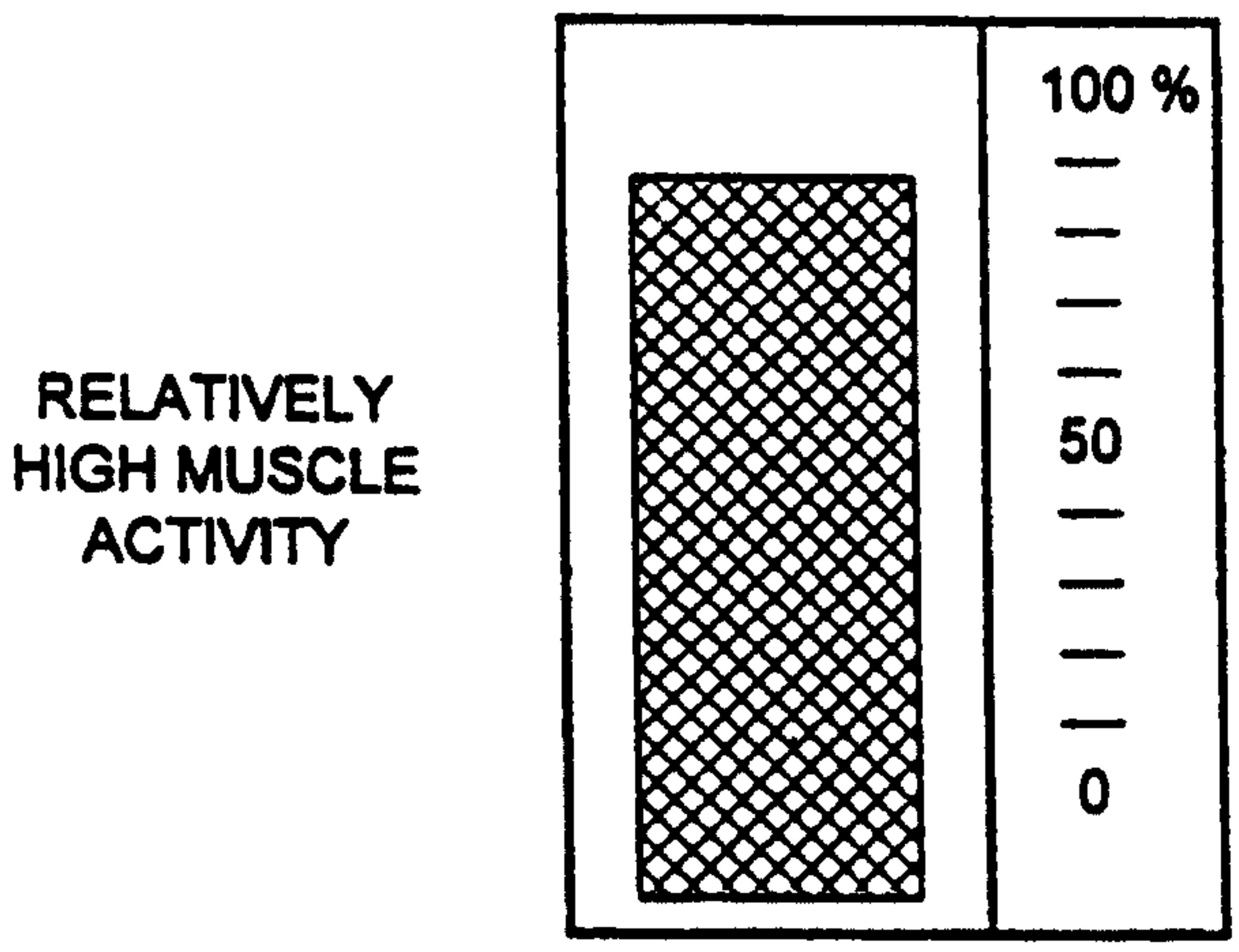
FIG. 1

SAMPLE DISPLAY OF THE PERCENT AWAKENING FEATURE



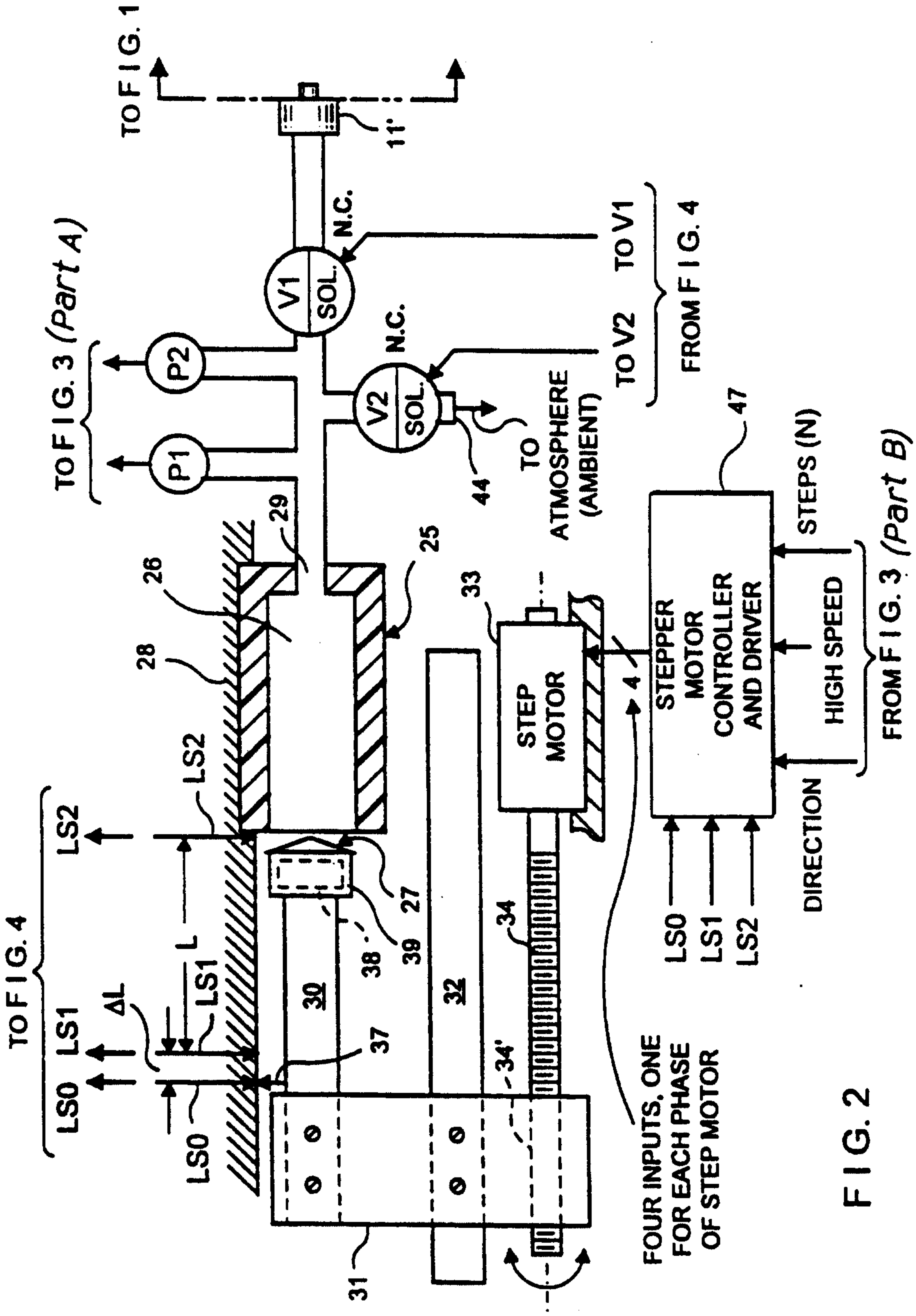
F I G. 1A

SAMPLE DISPLAY OF THE PERCENT AWAKENING FEATURE



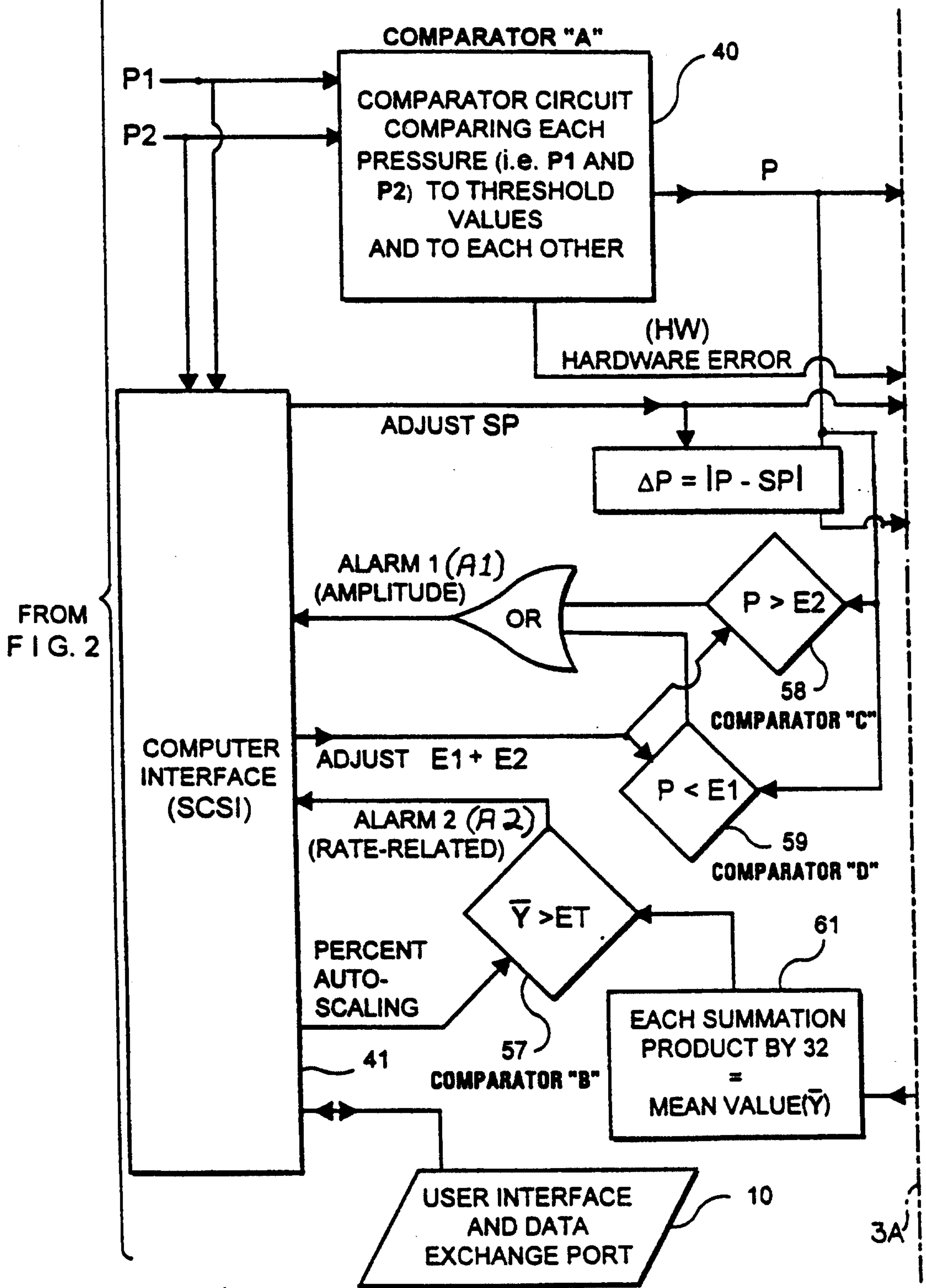
AUDIBLE AND VISUAL ALARMS WILL ISSUE WHEN THE PERCENTAGE REACHES 100%

F I G. 1B

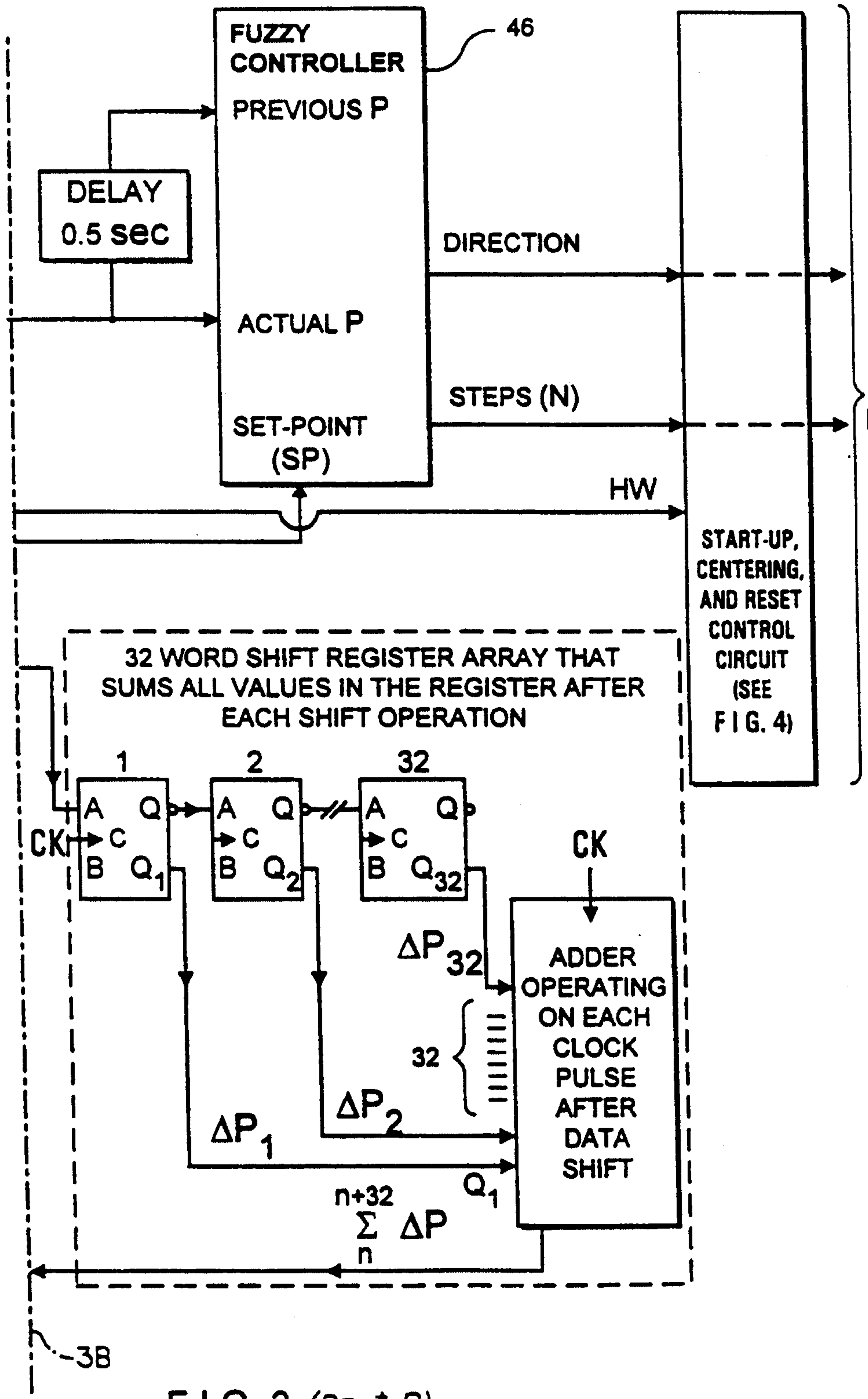

TO F I G. 1
11'
N.C.
V1
SOL.
TO V1
FROM F I G. 4
TO V2
N.C.
V2
SOL.
TO ATMOSPHERE (AMBIENT)
44
P2
P1
TO F I G. 3 (Part A)
29
26
25
28
33
STEP MOTOR
STEPPER MOTOR CONTROLLER AND DRIVER
47
STEPS (N)
HIGH SPEED
DIRECTION
FROM F I G. 3 (Part B)
LS0
LS1
LS2
4
FOUR INPUTS, ONE FOR EACH PHASE OF STEP MOTOR
LS2
L
ΔL
27
39
38
30
32
34
34'
37
31
TO F I G. 4

F I G. 2

INCIPIENT AWAKENING ALARM AND FUZZY-LOGIC MOTOR CONTROL CIRCUIT



F I G. 3 (Part A)


FUZZY CONTROLLER
46
PREVIOUS P
DELAY 0.5 sec
DIRECTION
ACTUAL P
STEPS (N)
SET-POINT (SP)
HW
TO FIG. 2
START-UP, CENTERING, AND RESET CONTROL CIRCUIT (SEE F I G. 4)
32 WORD SHIFT REGISTER ARRAY THAT SUMS ALL VALUES IN THE REGISTER AFTER EACH SHIFT OPERATION
1
2
32
A Q
C
B Q_1
A Q
C
B Q_2
A Q
C
B Q_{32}
CK
CK
ADDER OPERATING ON EACH CLOCK PULSE AFTER DATA SHIFT
ΔP_{32}
32
ΔP_2
ΔP_1
Q_1
$\sum_{n}^{n+32} \Delta P$
3B

F I G. 3 *(Part B)*

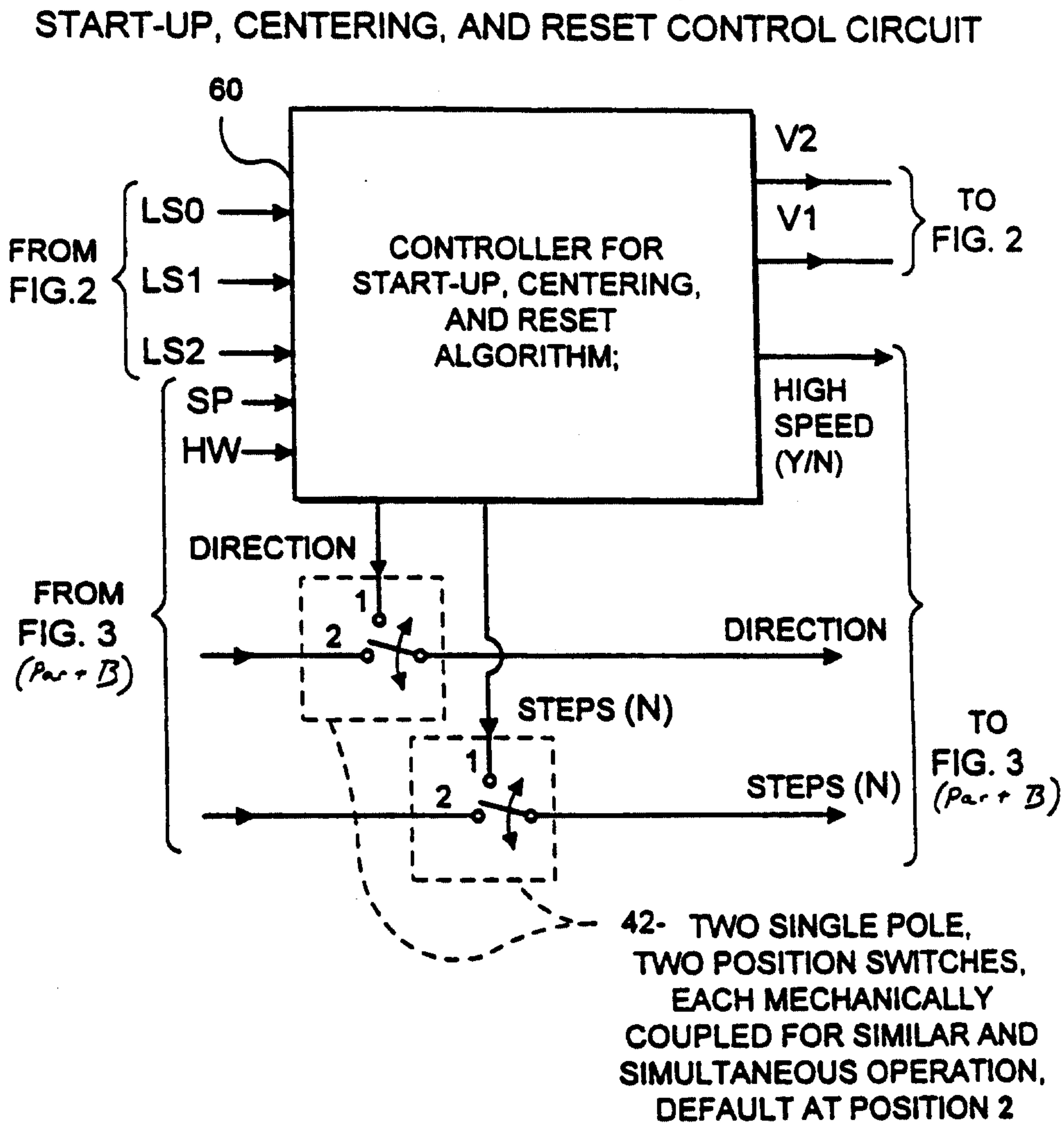

START-UP, CENTERING, AND RESET CONTROL CIRCUIT
60
CONTROLLER FOR START-UP, CENTERING, AND RESET ALGORITHM;
FROM FIG.2
LS0
LS1
LS2
SP
HW
V2
V1
TO FIG. 2
HIGH SPEED (Y/N)
DIRECTION
FROM FIG. 3 (Part B)
1
2
DIRECTION
STEPS (N)
STEPS (N)
TO FIG. 3 (Part B)
42- TWO SINGLE POLE, TWO POSITION SWITCHES, EACH MECHANICALLY COUPLED FOR SIMILAR AND SIMULTANEOUS OPERATION, DEFAULT AT POSITION 2

FIG. 4

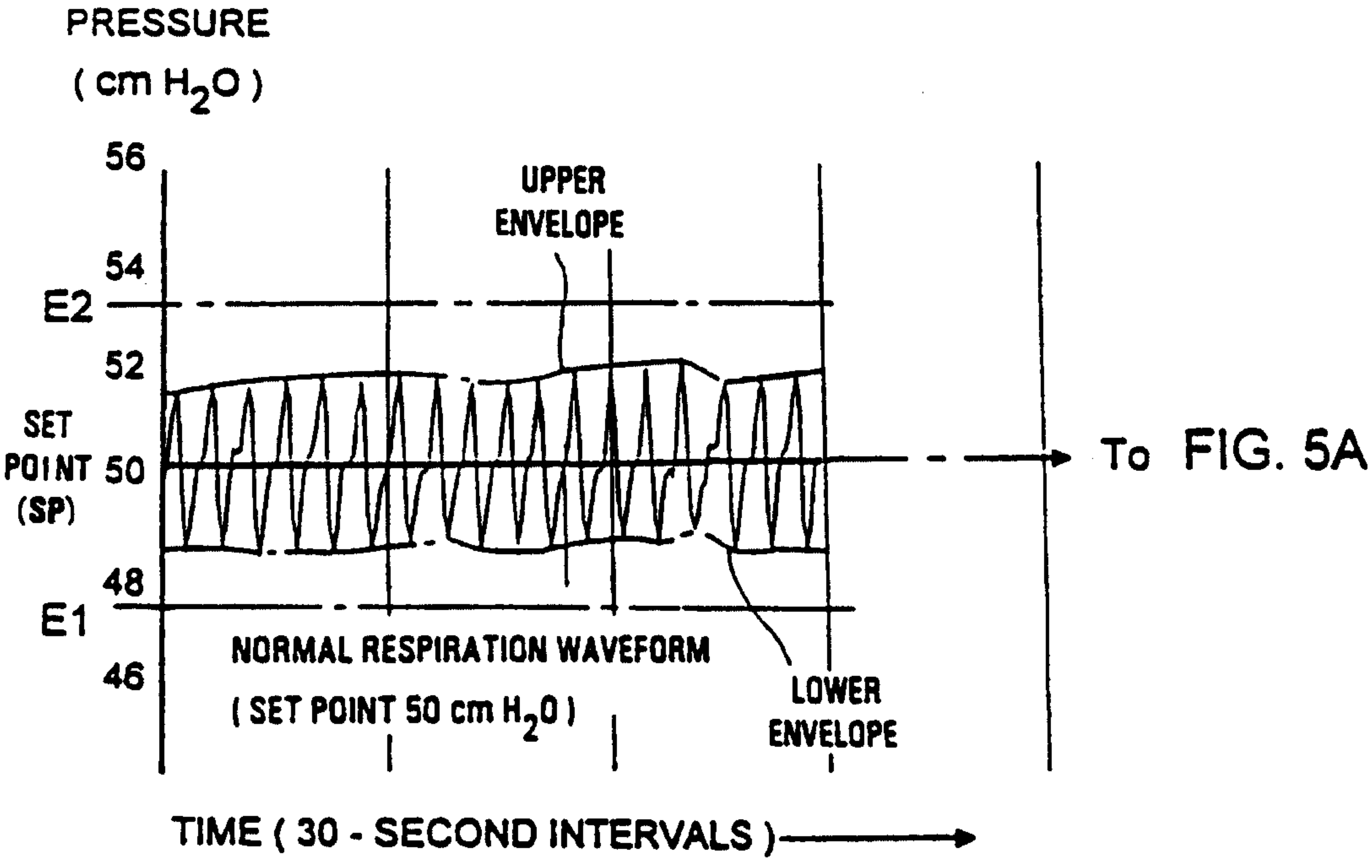

PRESSURE
(cm H_2O)
56
54
E2
52
SET POINT (SP) 50
48
E1
46
UPPER ENVELOPE
LOWER ENVELOPE
To FIG. 5A
NORMAL RESPIRATION WAVEFORM
(SET POINT 50 cm H_2O)
TIME (30 - SECOND INTERVALS)

FIG. 5

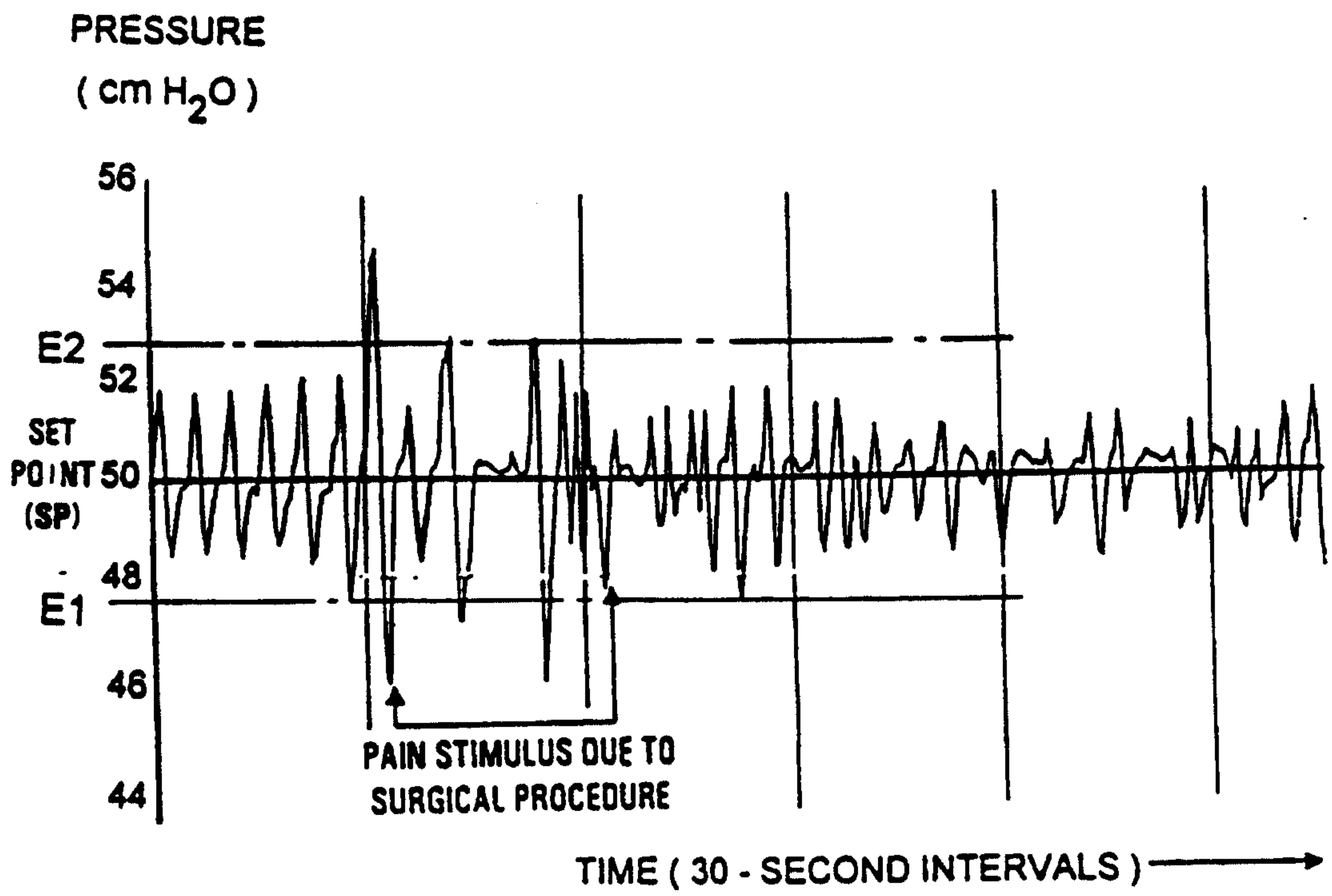

PRESSURE
(cm H_2O)
56
54
E2
52
SET POINT (SP) 50
48
E1
46
44
PAIN STIMULUS DUE TO SURGICAL PROCEDURE
TIME (30 - SECOND INTERVALS)

FIG. 5A

Set Points at E1 = -3 and E2 = 3 (and symmetrical around SP)

Amplitude Alarm Settings

E1 -3

E2 3

Derived Rate-Related Alarm Value:

ET 1.5

Empirical Values:			Calculated Values:			
Time	Actual P	Set Point (SP)	Deviation from SP	Absolute Value of deviation	32-Bit Summation	Alarm 2 (1=Yes)
0	51	50	1	1	n.a.	n.a.
1	52	50	2	2	n.a.	n.a.
2	54	50	4	4	n.a.	n.a.
3	55	50	5	5	n.a.	n.a.
4	49	50	-1	1	n.a.	n.a.
5	45	50	-5	5	n.a.	n.a.
6	47	50	-3	3	n.a.	n.a.
7	49	50	-1	1	n.a.	n.a.
8	51	50	1	1	n.a.	n.a.
9	53	50	3	3	n.a.	n.a.
10	50	50	0	0	n.a.	n.a.
11	45	50	-5	5	n.a.	n.a.
12	43	50	-7	7	n.a.	n.a.
13	45	50	-5	5	n.a.	n.a.
14	45	50	-5	5	n.a.	n.a.
15	48	50	-2	2	n.a.	n.a.
16	49	50	-1	1	n.a.	n.a.
17	52	50	2	2	n.a.	n.a.
18	53	50	3	3	n.a.	n.a.
19	55	50	5	5	n.a.	n.a.
20	52	50	2	2	n.a.	n.a.
21	51	50	1	1	n.a.	n.a.
22	49	50	-1	1	n.a.	n.a.
23	48	50	-2	2	n.a.	n.a.
24	46	50	-4	4	n.a.	n.a.
25	49	50	-1	1	n.a.	n.a.
26	51	50	1	1	n.a.	n.a.
27	52	50	2	2	n.a.	n.a.
28	51	50	1	1	n.a.	n.a.
29	51	50	1	1	n.a.	n.a.
30	48	50	-2	2	n.a.	n.a.
31	45	50	-5	5	n.a.	n.a.
32	46	50	-4	4	2.75	1
33	51	50	1	1	2.75	1
34	54	50	4	4	2.8125	1
35	54	50	4	4	2.8125	1
36	52	50	2	2	2.71875	1
37	52	50	2	2	2.75	1
38	51	50	1	1	2.625	1
39	49	50	-1	1	2.5625	1

F I G. 6A

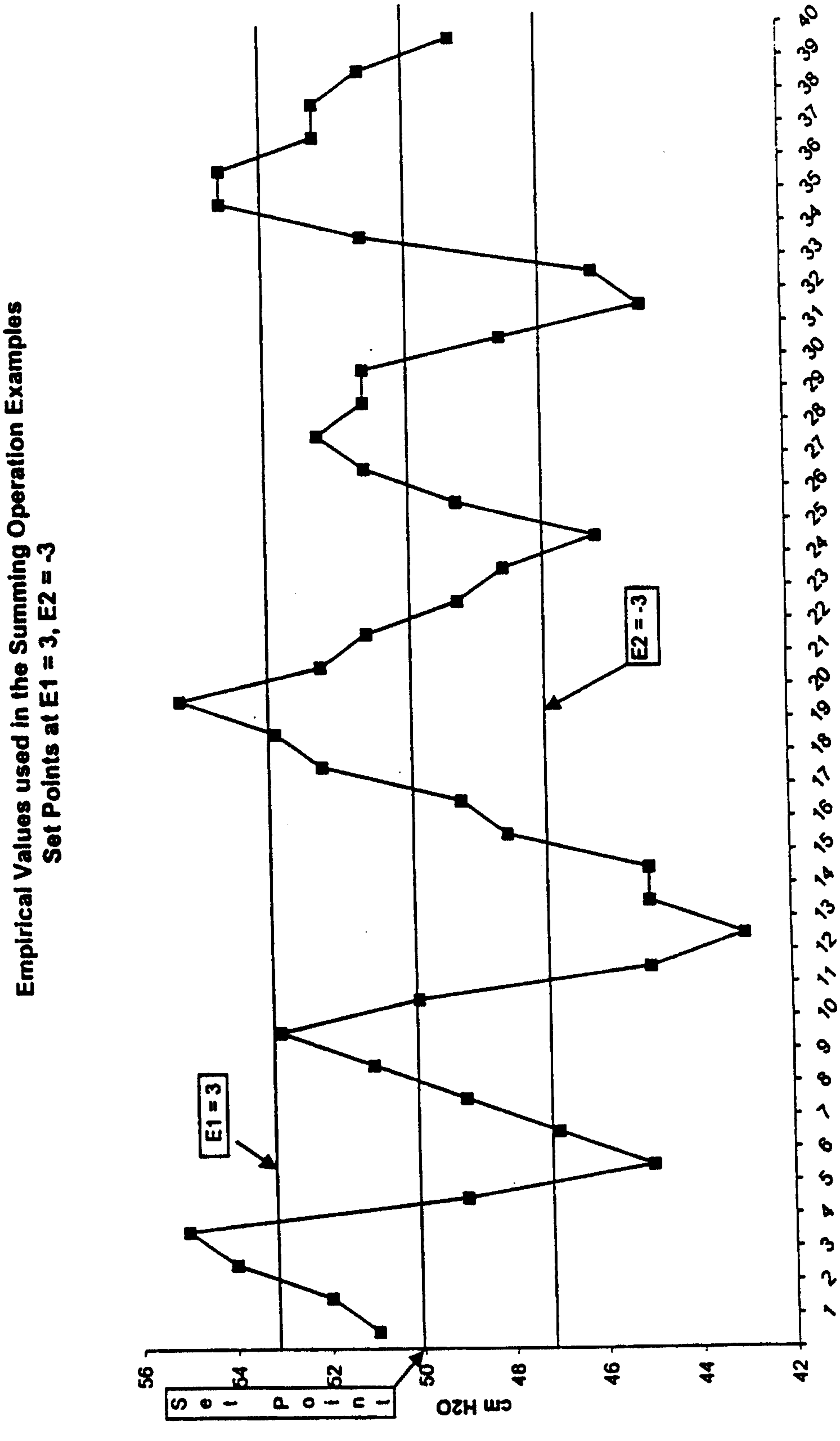

Empirical Values used in the Summing Operation Examples
Set Points at E1 = 3, E2 = -3
E1 = 3
E2 = -3
Set Point
cm H2O
56
54
52
50
48
46
44
42
Time
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40

FIG. 6B

Set Points at E1 = -5 and E2 = 5.5

Amplitude Alarm Settings
E1 -5
E2 5.5

Derived Rate-Related Alarm Value:
ET 2.625

Empirical Values: Time	Actual P	Set Point (SP)	Deviation from SP	Calculated Values: Absolute Value of deviation	32-Bit Summation	Alarm 2 (1=Yes)
0	51	50	1	1	n.a.	n.a.
1	52	50	2	2	n.a.	n.a.
2	54	50	4	4	n.a.	n.a.
3	55	50	5	5	n.a.	n.a.
4	49	50	-1	1	n.a.	n.a.
5	45	50	-5	5	n.a.	n.a.
6	47	50	-3	3	n.a.	n.a.
7	49	50	-1	1	n.a.	n.a.
8	51	50	1	1	n.a.	n.a.
9	53	50	3	3	n.a.	n.a.
10	50	50	0	0	n.a.	n.a.
11	45	50	-5	5	n.a.	n.a.
12	43	50	-7	7	n.a.	n.a.
13	45	50	-5	5	n.a.	n.a.
14	45	50	-5	5	n.a.	n.a.
15	48	50	-2	2	n.a.	n.a.
16	49	50	-1	1	n.a.	n.a.
17	52	50	2	2	n.a.	n.a.
18	53	50	3	3	n.a.	n.a.
19	55	50	5	5	n.a.	n.a.
20	52	50	2	2	n.a.	n.a.
21	51	50	1	1	n.a.	n.a.
22	49	50	-1	1	n.a.	n.a.
23	48	50	-2	2	n.a.	n.a.
24	46	50	-4	4	n.a.	n.a.
25	49	50	-1	1	n.a.	n.a.
26	51	50	1	1	n.a.	n.a.
27	52	50	2	2	n.a.	n.a.
28	51	50	1	1	n.a.	n.a.
29	51	50	1	1	n.a.	n.a.
30	48	50	-2	2	n.a.	n.a.
31	45	50	-5	5	n.a.	n.a.
32	46	50	-4	4	2.75	1
33	51	50	1	1	2.75	1
34	54	50	4	4	2.8125	1
35	54	50	4	4	2.8125	1
36	52	50	2	2	2.71875	1
37	52	50	2	2	2.75	1
38	51	50	1	1	2.625	0
39	49	50	-1	1	2.5625	0

FIG. 6C

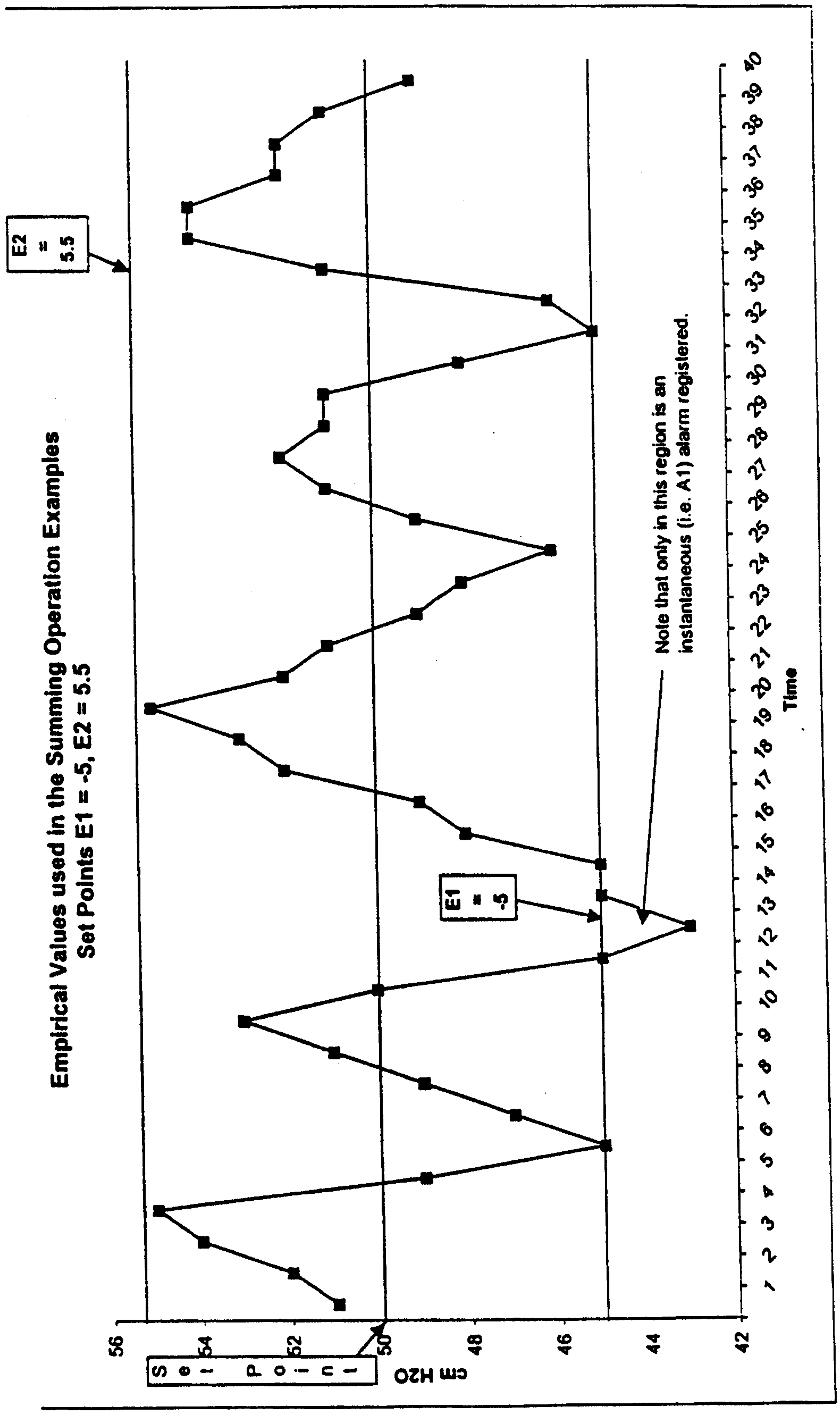

Empirical Values used in the Summing Operation Examples
Set Points E1 = -5, E2 = 5.5
E2 = 5.5
E1 = -5
Set Point
cm H2O
Time
Note that only in this region is an instantaneous (i.e. A1) alarm registered.

FIG. 6D

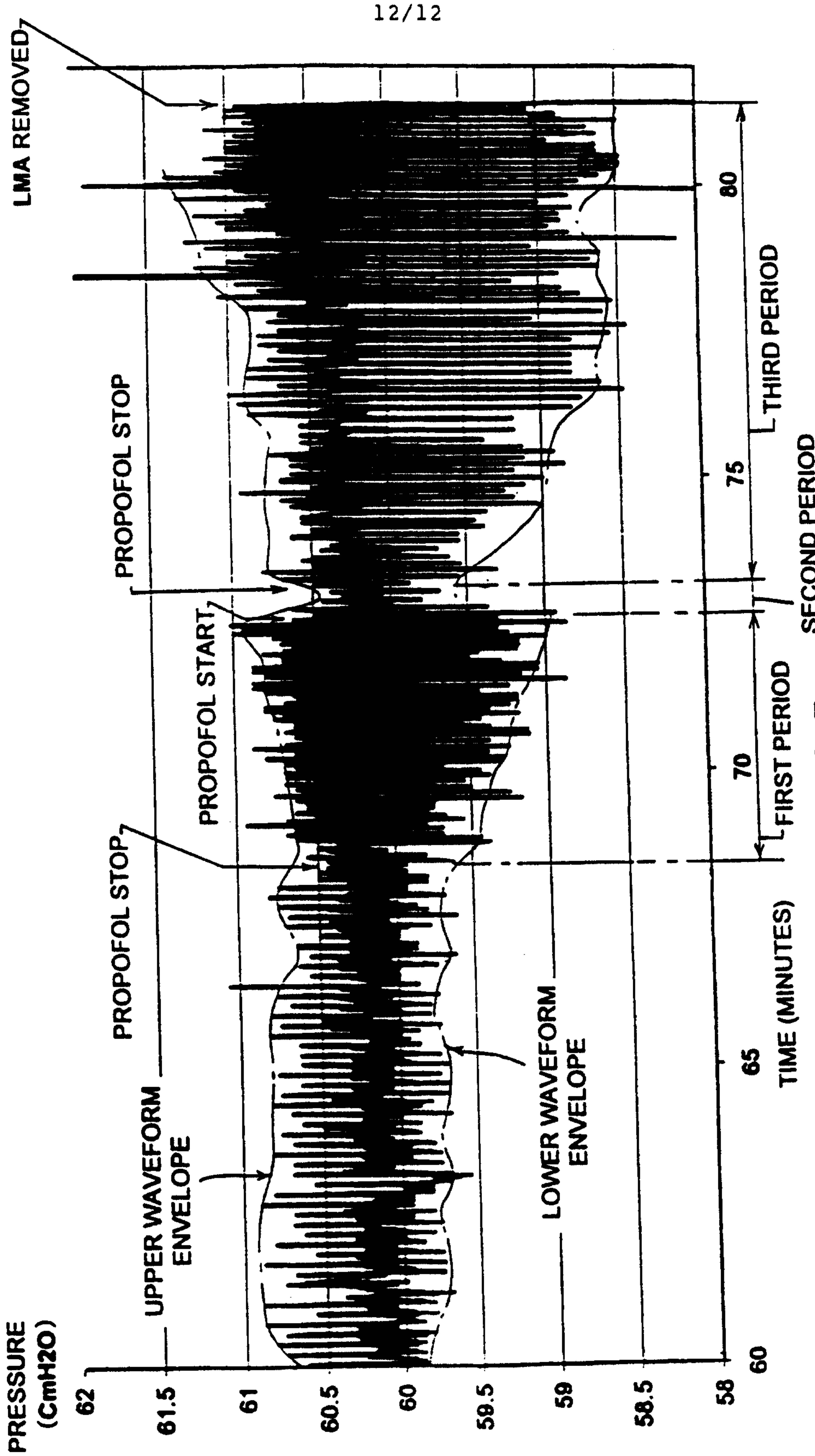
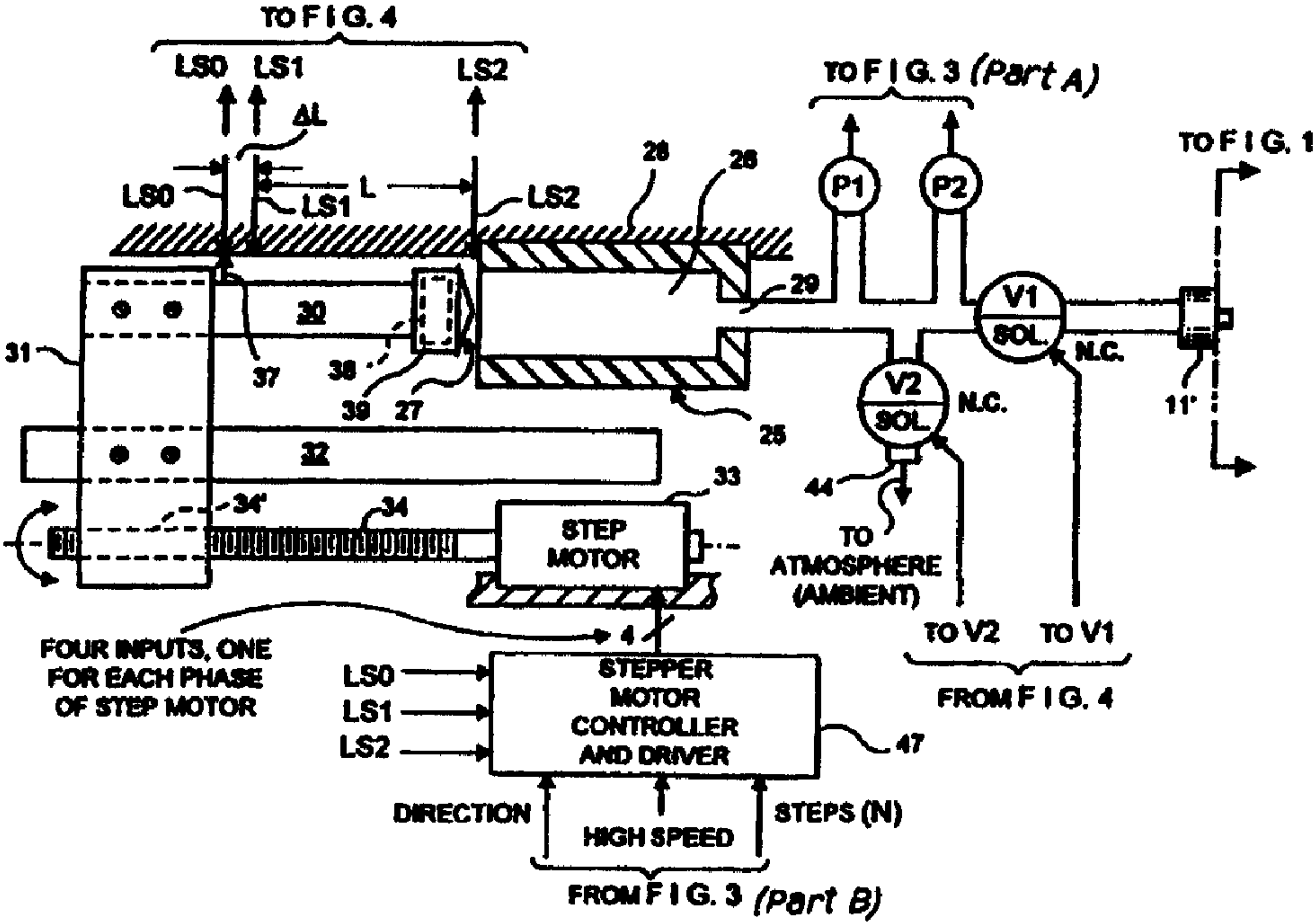

Patient 5
PRESSURE (CmH2O)
62
61.5
61
60.5
60
59.5
59
58.5
58
UPPER WAVEFORM ENVELOPE
LOWER WAVEFORM ENVELOPE
PROPOFOL STOP
PROPOFOL START
PROPOFOL STOP
LMA REMOVED
FIRST PERIOD
SECOND PERIOD
THIRD PERIOD
60
65
70
75
80
TIME (MINUTES)

FIG. 7


TO F I G. 4
LS0
LS1
LS2
ΔL
L
TO F I G. 3 (Part A)
P1
P2
TO F I G. 1
28
26
29
V1
SOL.
N.C.
V2
SOL.
N.C.
30
31
37
38
39
27
25
11'
32
33
44
34'
34
STEP MOTOR
TO ATMOSPHERE (AMBIENT)
TO V2
TO V1
FROM F I G. 4
FOUR INPUTS, ONE FOR EACH PHASE OF STEP MOTOR
4
STEPPER MOTOR CONTROLLER AND DRIVER
47
DIRECTION
HIGH SPEED
STEPS (N)
FROM F I G. 3 (Part B)