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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
Rad: 05-088375- 00003-0000
Fec. 2025-12-15 15:23:13 Dep. 2020 NUECREACIONES
Tra. 11 PATENTE(Y)
Evs. 378 FASE NACIONAL
Art. 639 PETICION 1 0103 2

Señora

Alix Carmenza Céspedes de Vergel

Jefe de División de Nuevas Creaciones

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

E. _____ S. _____ D. _____

Referencia: Expediente No. 05.088.375

Solicitud de Patente de Invención titulada: "Dispositivo dispensador de medicamento con una pantalla indicadora del estado del reservorio de medicamento interno."

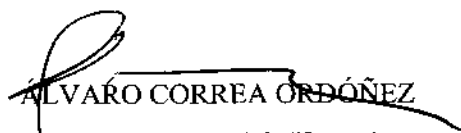
Solicitante: Norton Healthcare, Inc.

SOLICITUD DE EXAMEN DE PATENTABILIDAD SEGÚN EL ARTÍCULO 44 DE LA DECISIÓN

486. GACETA NO. 566

ÁLVARO CORREA ORDÓÑEZ, mayor de edad y vecino de Bogotá D.C., identificado según aparece al pie de mi firma, en mi condición de apoderado de la sociedad arriba mencionada, solicito que se examine la invención de la referencia según los requisitos de patentabilidad previstos en la Decisión 486 de la Comisión de la Comunidad Andina de Naciones. Adjunto recibo de caja por valor de \$388.000 para cubrir la tasa correspondiente según la Resolución 35582 del 28 de diciembre de 2005.

Atentamente,


ÁLVARO CORREA ORDÓÑEZ
C.C.No.79.143.366 de Usaquén
T.P.20.281

Anexo: Recibo de caja No. 06-61022 por valor de \$388.000

0-10

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

153

NIT : 000176009-2

RECIBO OFICIAL DE CAJA : 06 - 61,922
FECHA : AGOSTO 11 DE 2006

***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	Nº. PAGO	FECHA PGO	Vr. PAGO
ORLANDO LINARES	CONSIGNACION	BANCO POPULAR	050-00110-6	296400	11/08/2006	296,400.00
ORLANDO LINARES	CONSIGNACION	BANCO POPULAR	050-00110-6	47638029	11/08/2006	2,576,400.00
ORLANDO LINARES	CONSIGNACION	BANCO POPULAR	050-00110-6	47638032	11/08/2006	64,415,000.00

***** CONCEPTO *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-01	SOLICITUDES	
		85 EXAMEN DE PATENTABILIDAD DE INVEN	388,000.00
		TOTAL :	\$ 388,000.00

SON: TRESCIENTOS OCHENTA Y OCHO MIL PESOS

RESPONSABLE :

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____

DIVISIÓN DE NUEVAS CREACIONES

RADICACIÓN EXPEDIENTE No. 05-88375

EL EXTRACTO DE LA PRESENTE SOLICITUD DE **PATENTE DE INVENCION**

FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No **566** DE

FECHA **31 DE JULIO DE 2006** EL TÉRMINO HÁBIL SEÑALADO POR LA LEY

EXPIRA EL **26 DE OCTUBRE DE 2006**

NOTA: Dentro del plazo de los seis (6) meses siguientes a partir de la fecha de publicación en la gaceta de Propiedad Industrial, deberá solicitar y cancelar el examen de patentabilidad so pena de que la solicitud caiga en abandono, de acuerdo con lo establecido en el Artículo 44 de la Decisión 486/2000.

SE PRESENTARON OPOSICIONES POR PARTE DE TERCEROS.

SI _____

NO X



US005404871A

United States Patent [19]

Goodman et al.

[11] Patent Number: 5,404,871

[45] Date of Patent: Apr. 11, 1995

[54] DELIVERY OF AEROSOL MEDICATIONS FOR INSPIRATION

[75] Inventors: David E. Goodman, Brookline; Reid M. Rubsamen, Boston, both of Mass.

[73] Assignee: Aradigm, Hayward, Calif.

[21] Appl. No.: 664,758

[22] Filed: Mar. 5, 1991

[51] Int. Cl.⁶ A61M 11/00

[52] U.S. Cl. 128/200.14; 128/200.23; 128/204.23; 128/205.23

[58] Field of Search 128/200.14, 200.23, 128/203.12, 204.26, 204.23, 204.21, 205.23

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Primary Examiner—Edgar S. Burr

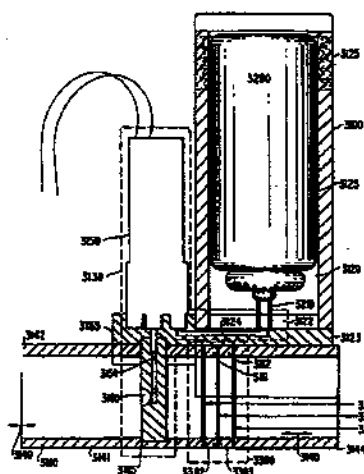
Assistant Examiner—Aaron J. Lewis

Attorney, Agent, or Firm—Karl Bozicevic; Fish & Richardson

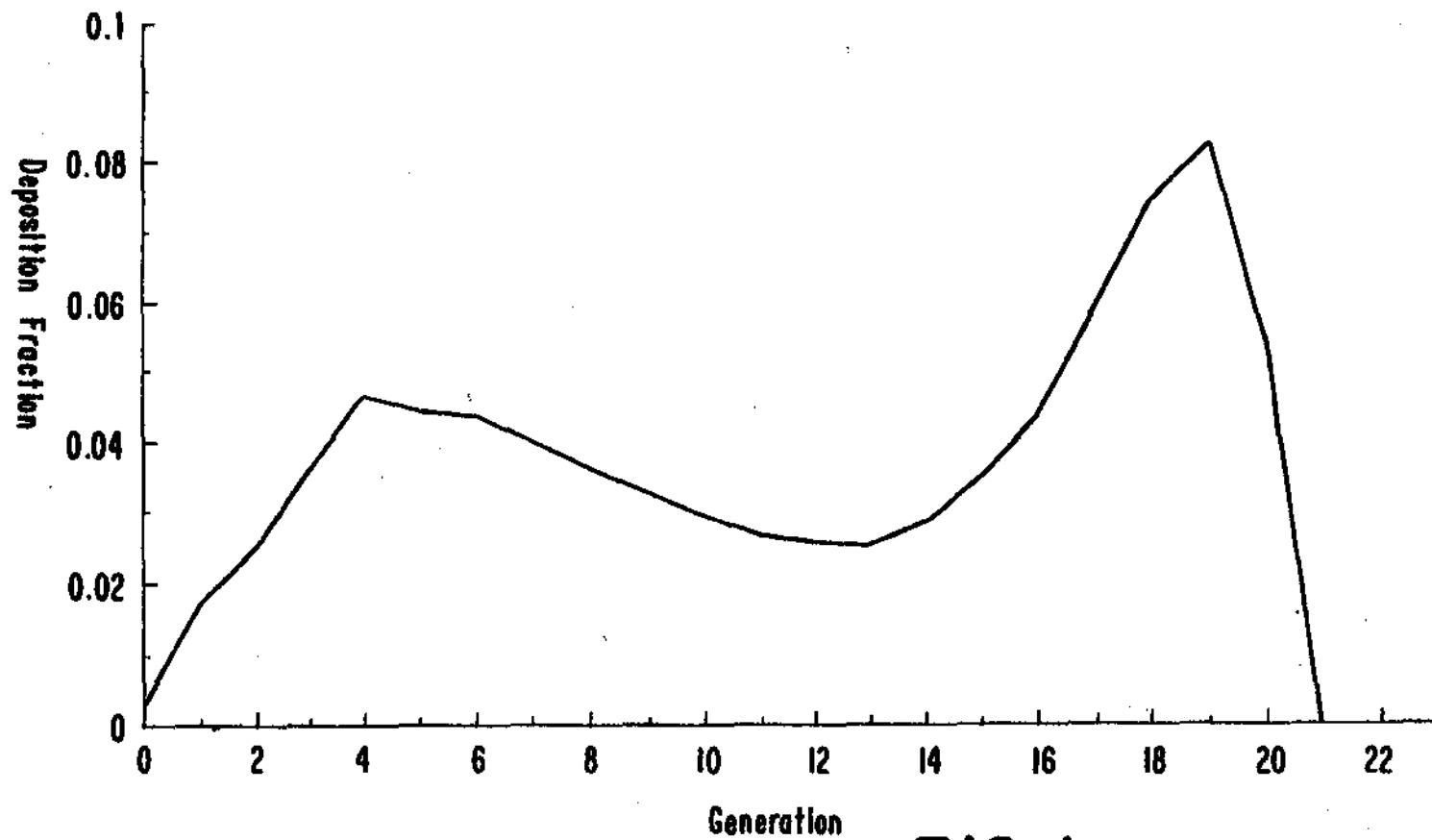
[57] ABSTRACT

Apparatus and methods for delivering an amount of aerosolized medicine for inspiration by a patient in response to the occurrence of appropriate delivery point or points in the patient's detected breath flow. The aerosol medication may be administered as one or more pulses having a pulse width, shape, and frequency that will maximize the respirable fraction of the aerosolized compound being administered. The delivery point or points may be predetermined or determined from a prior inspiratory flow for depositing the selected medication at one or more desired locations in the patient's airway. Determined delivery points are recursively lowered for each inspiratory flow that does not satisfy one of the predetermined and previously lowered threshold. Changes in the patient's breath flow patterns during the course of an aerosolized medication inspiration therapy program may be detected and used to adjust the controlled amount of medication to be delivered in a given administration and/or to inform the patient of the patient's condition or change in condition. The device also may contain a library of administration protocols or operating parameters for different medications and a means for identifying from the canister the medicinal contents of the canister for customizing operation of the apparatus.

132 Claims, 17 Drawing Sheets



$d_{ae} = 5 \mu m$
 $V_t = 700 \text{ ml}$
 $V_{ins} = 500 \text{ ml/sec}$

**FIG. 1**

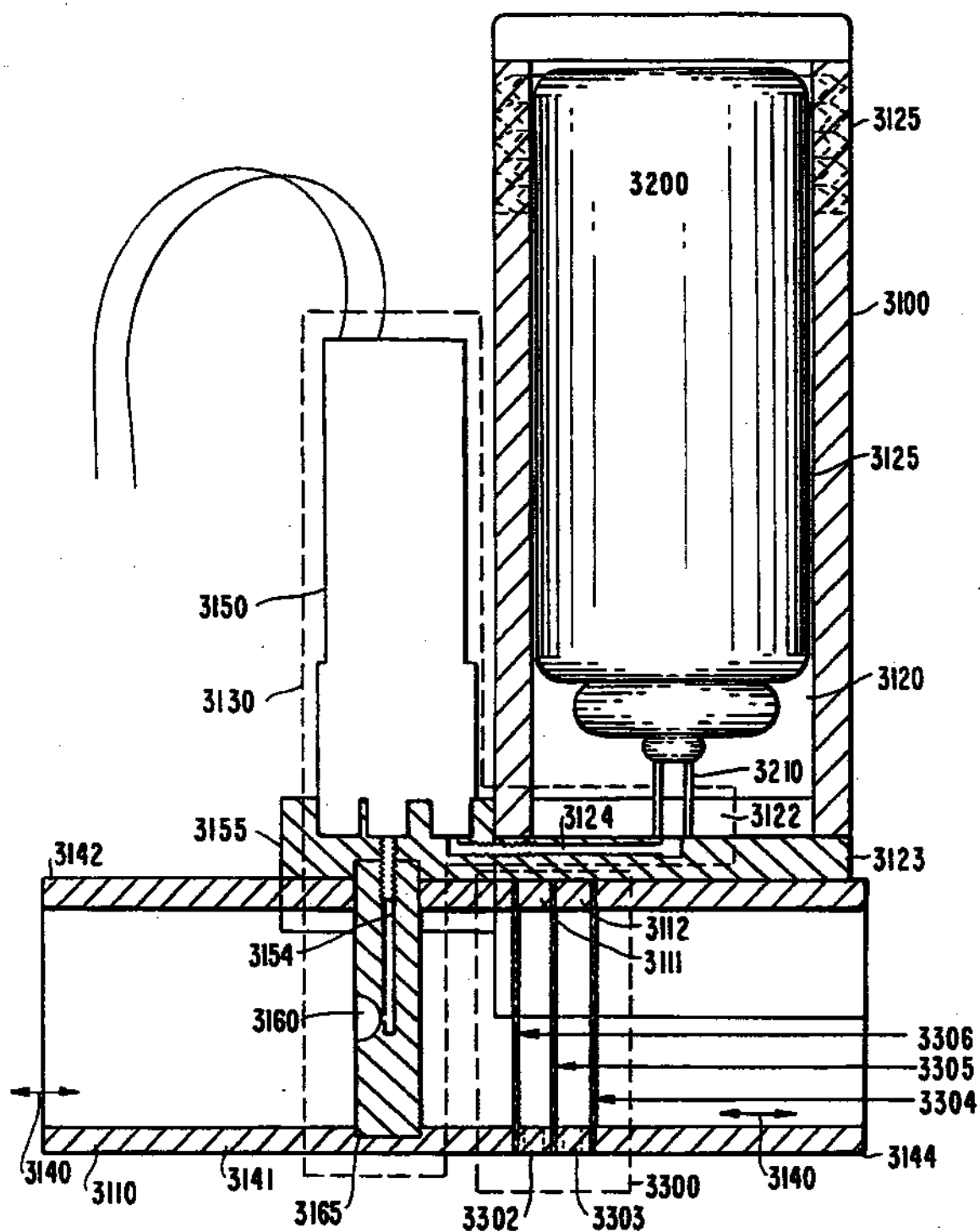


FIG. 2A

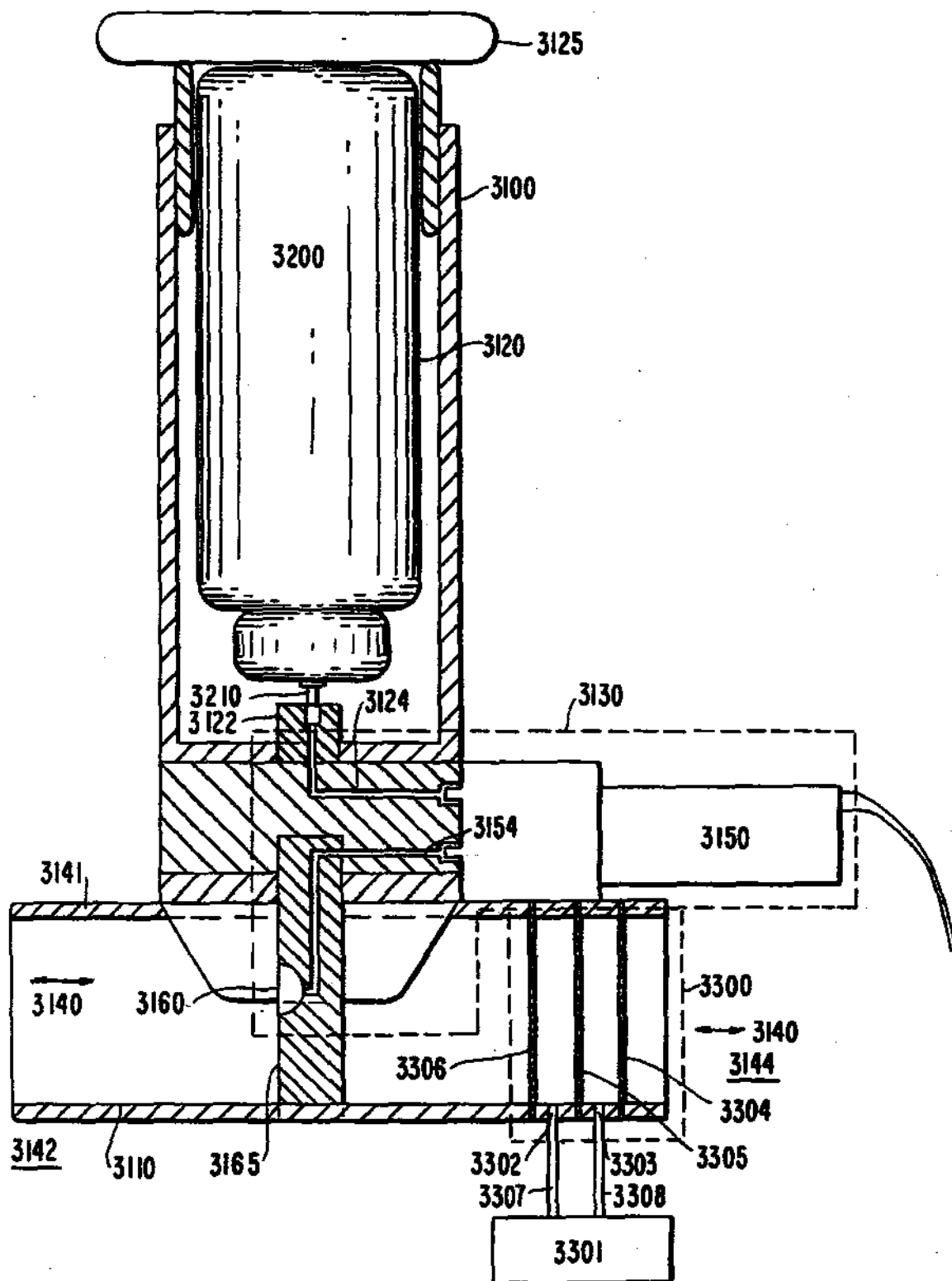


FIG. 2B

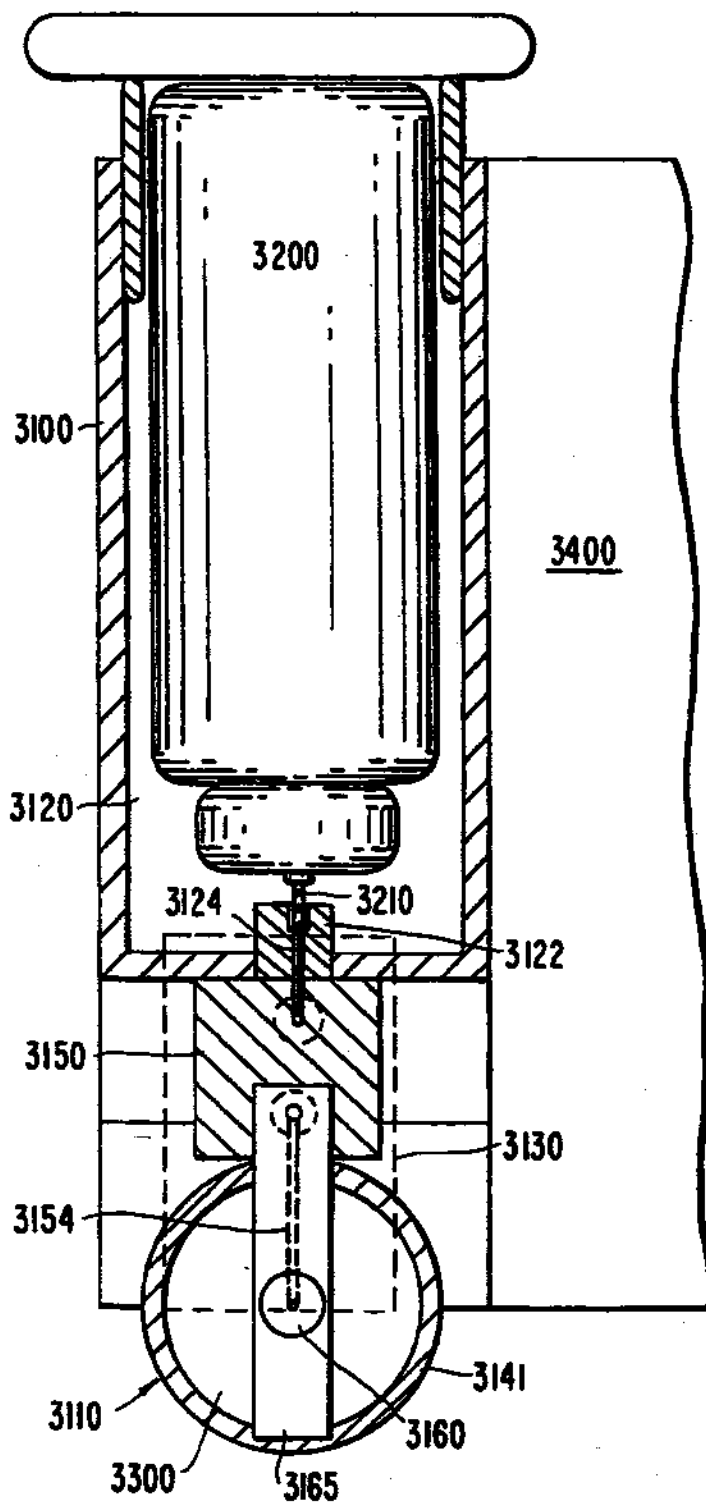
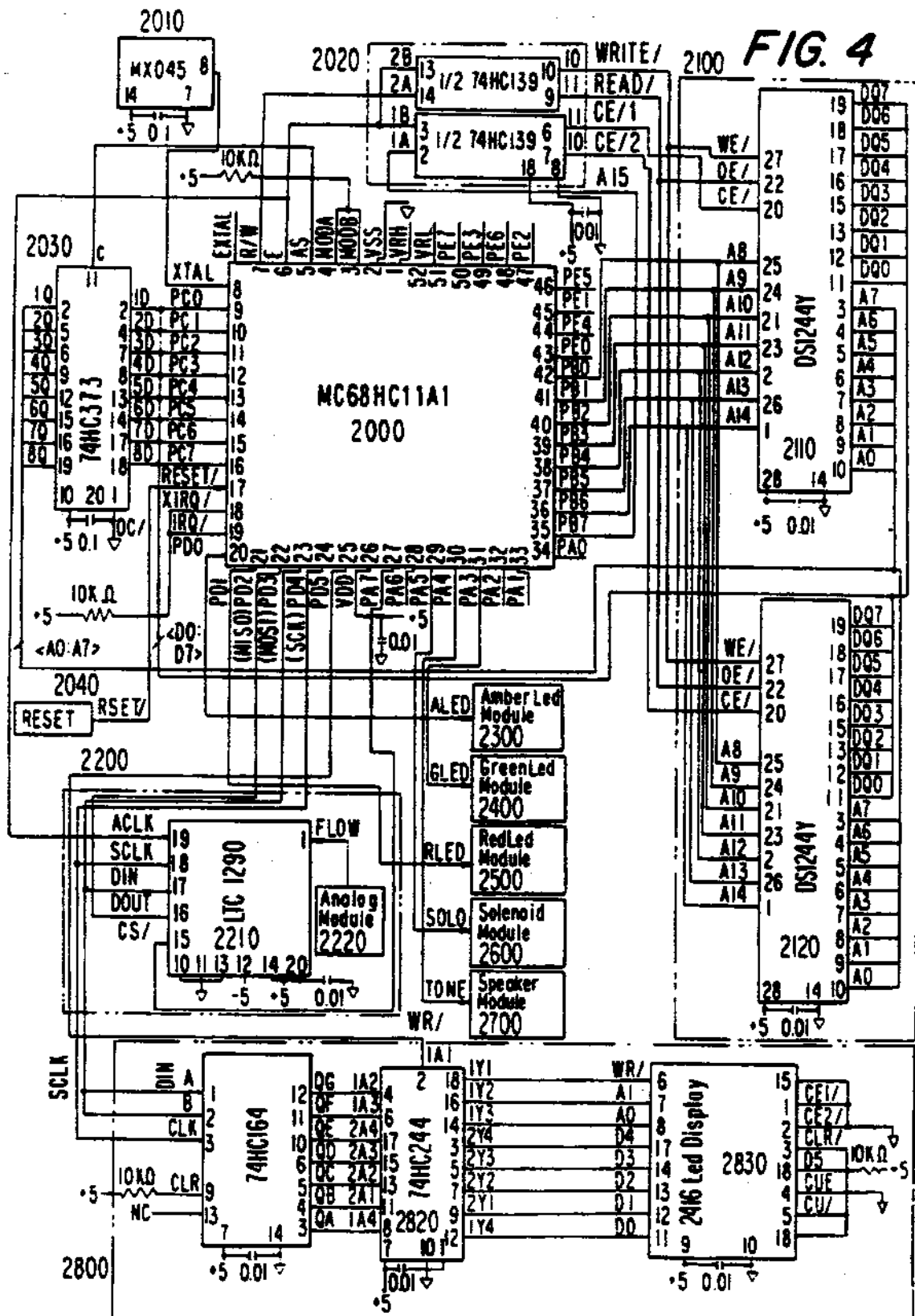


FIG. 3



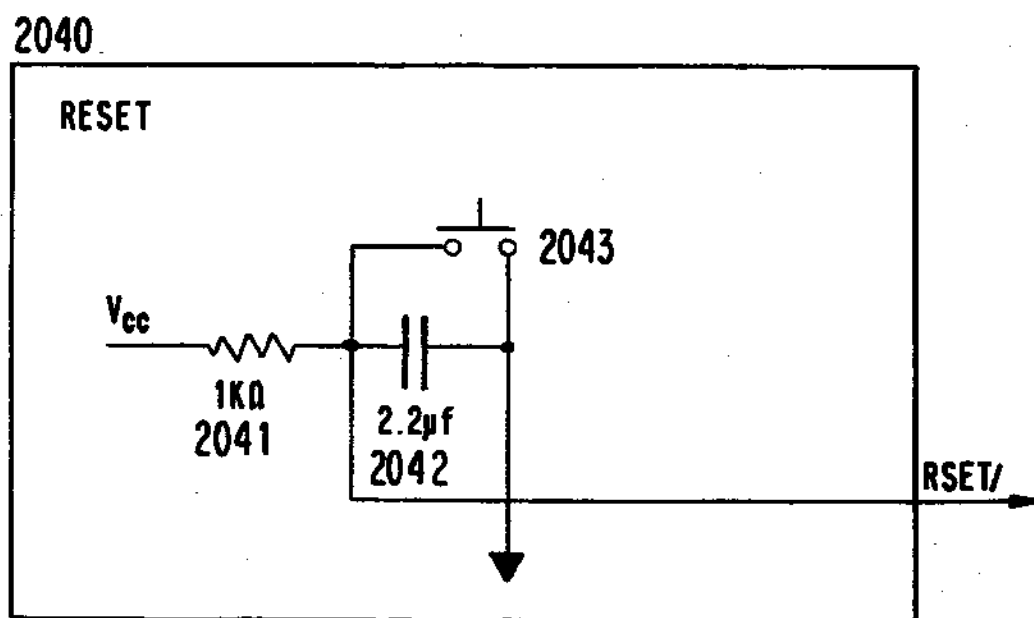
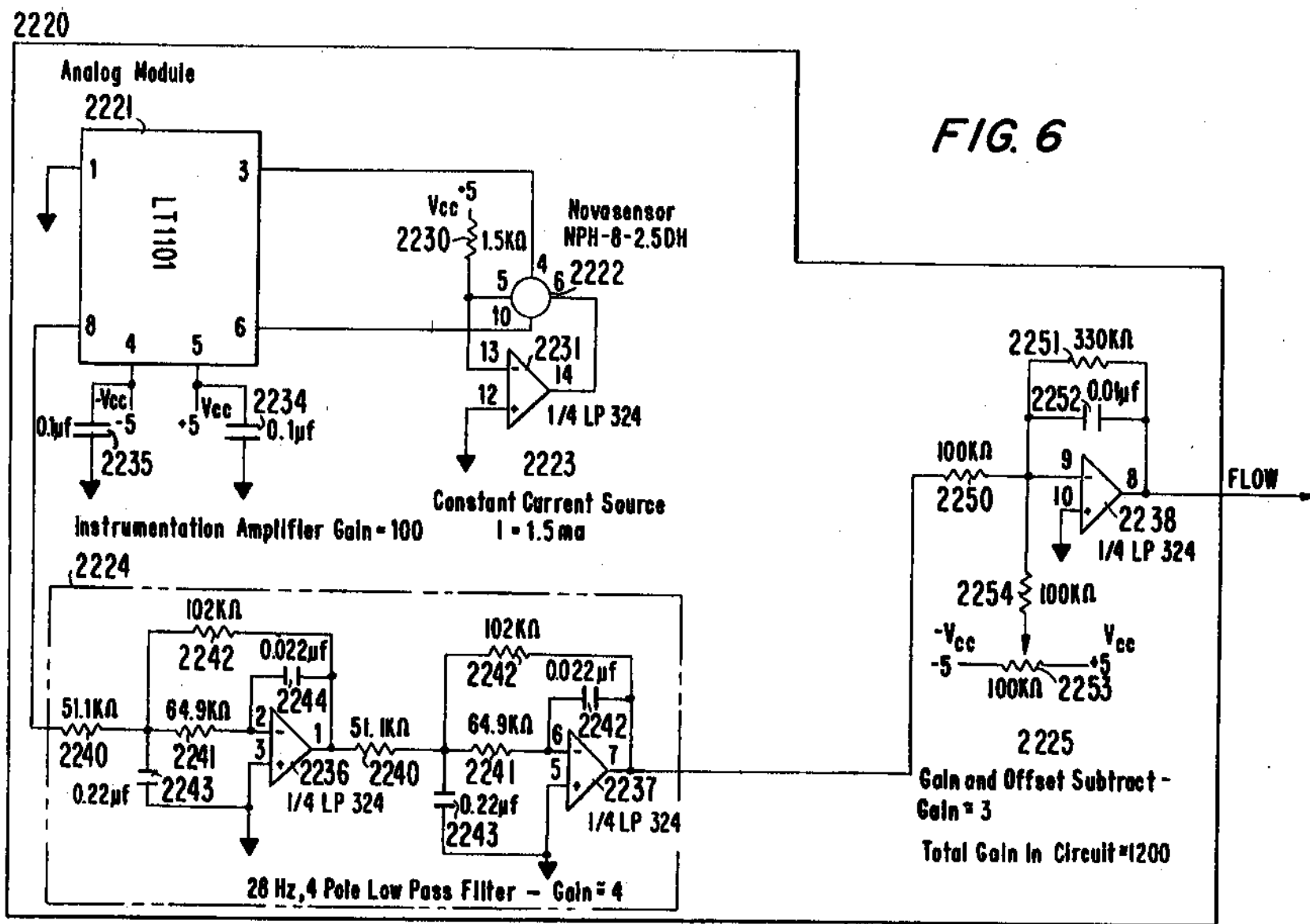


FIG. 5

FIG. 6



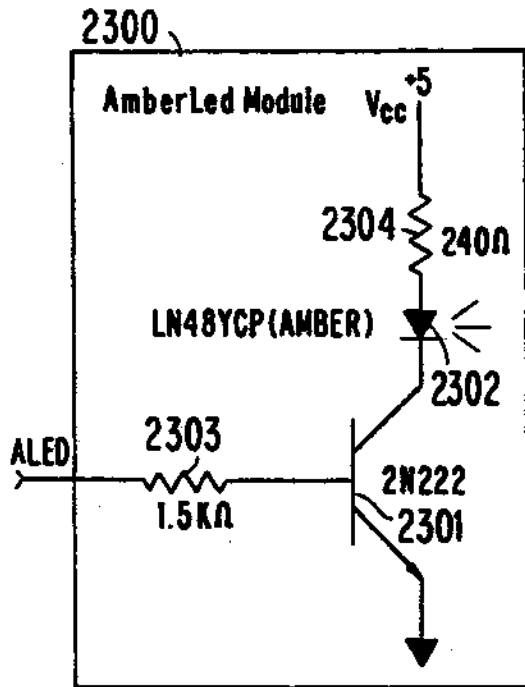


FIG. 7

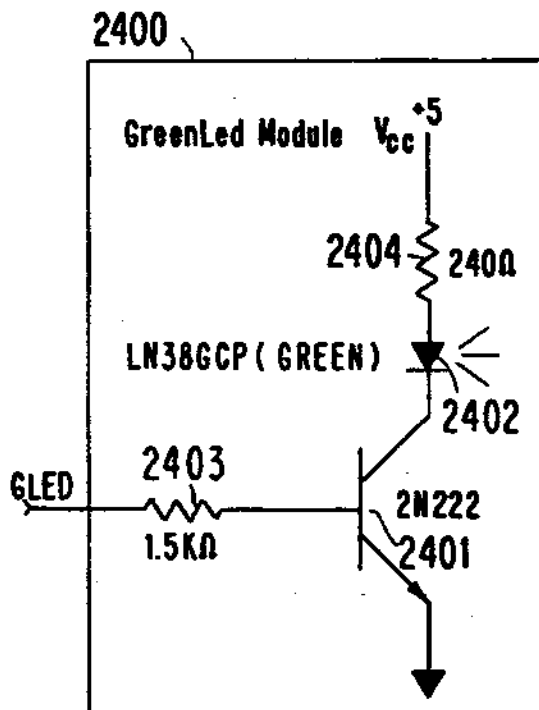


FIG. 8

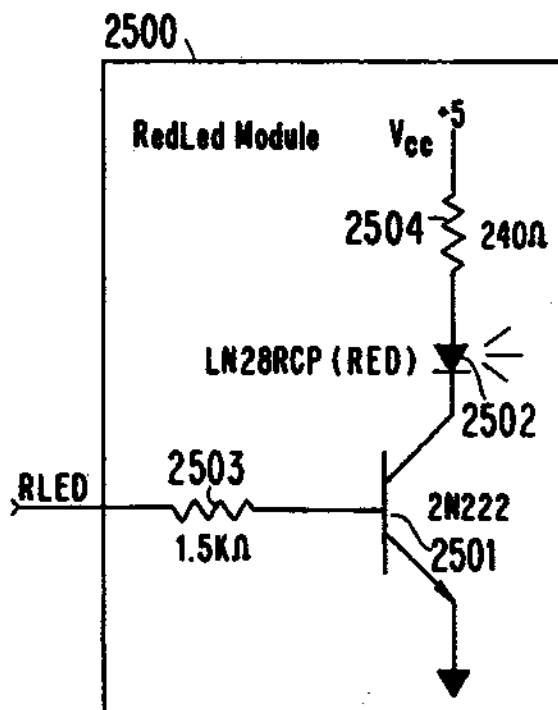


FIG. 9

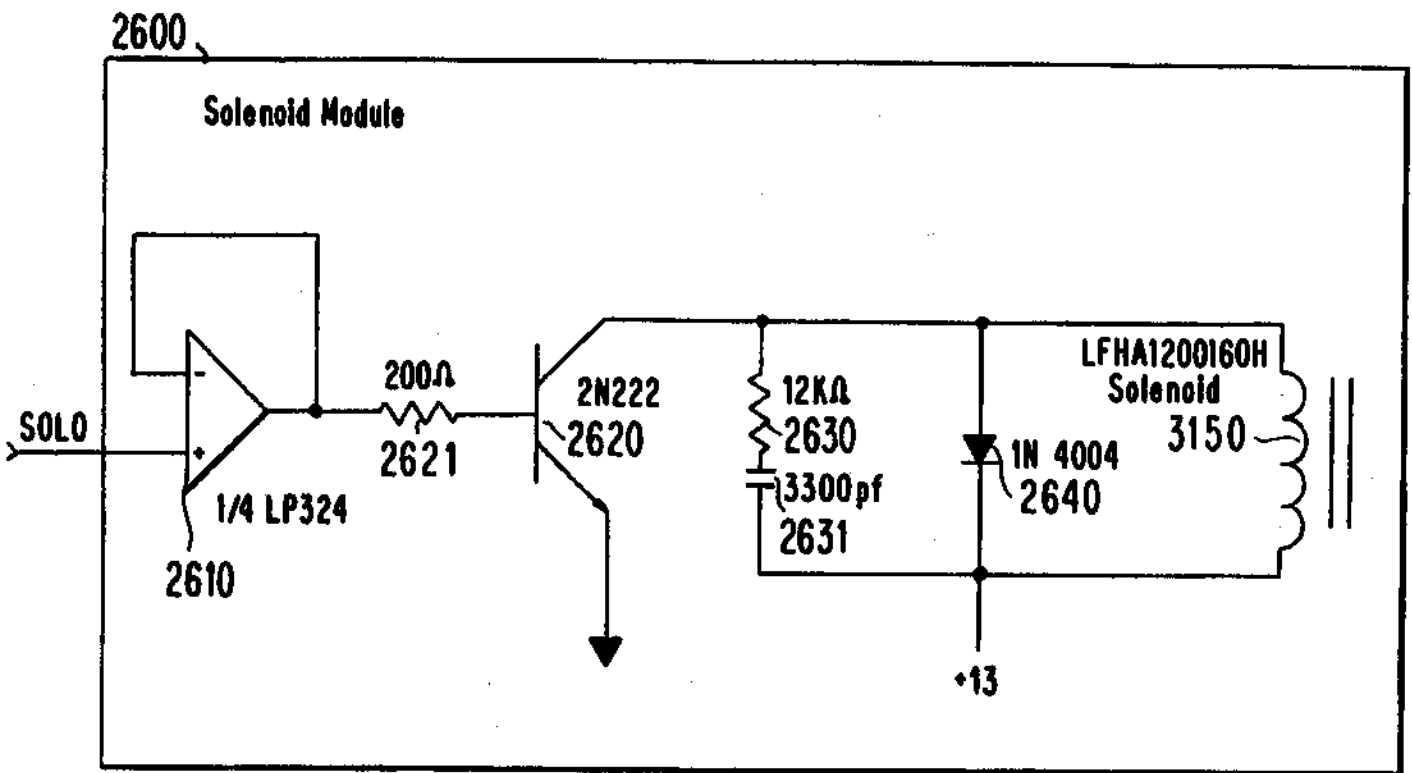


FIG. 10

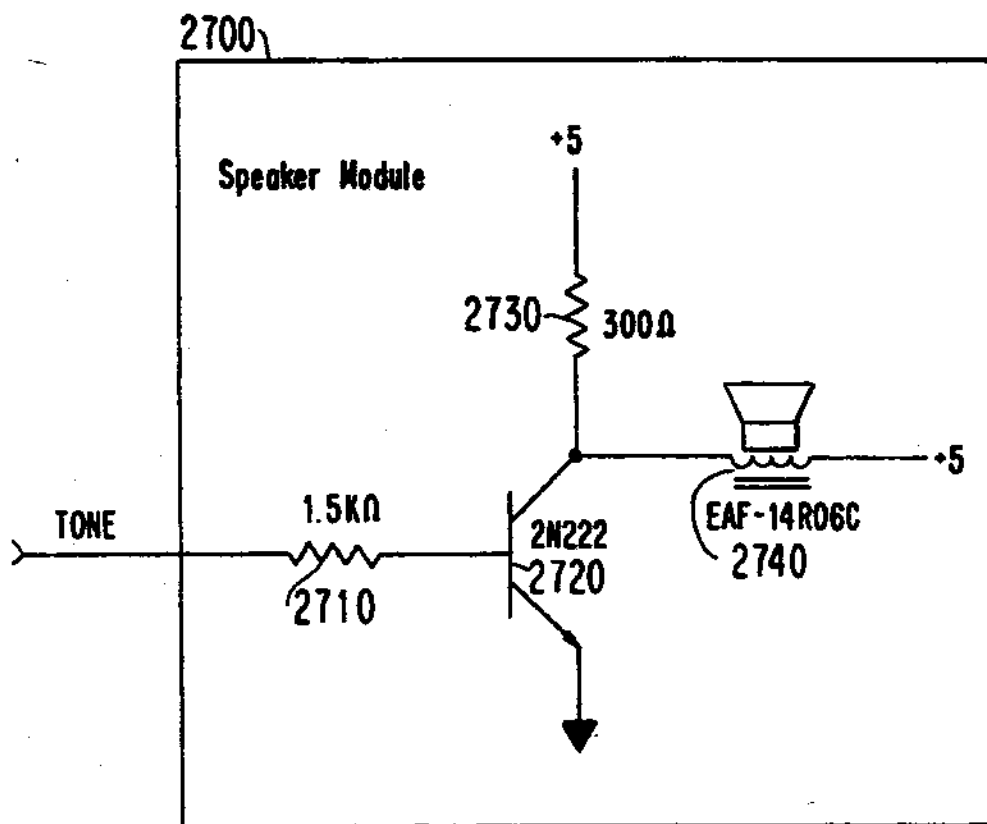
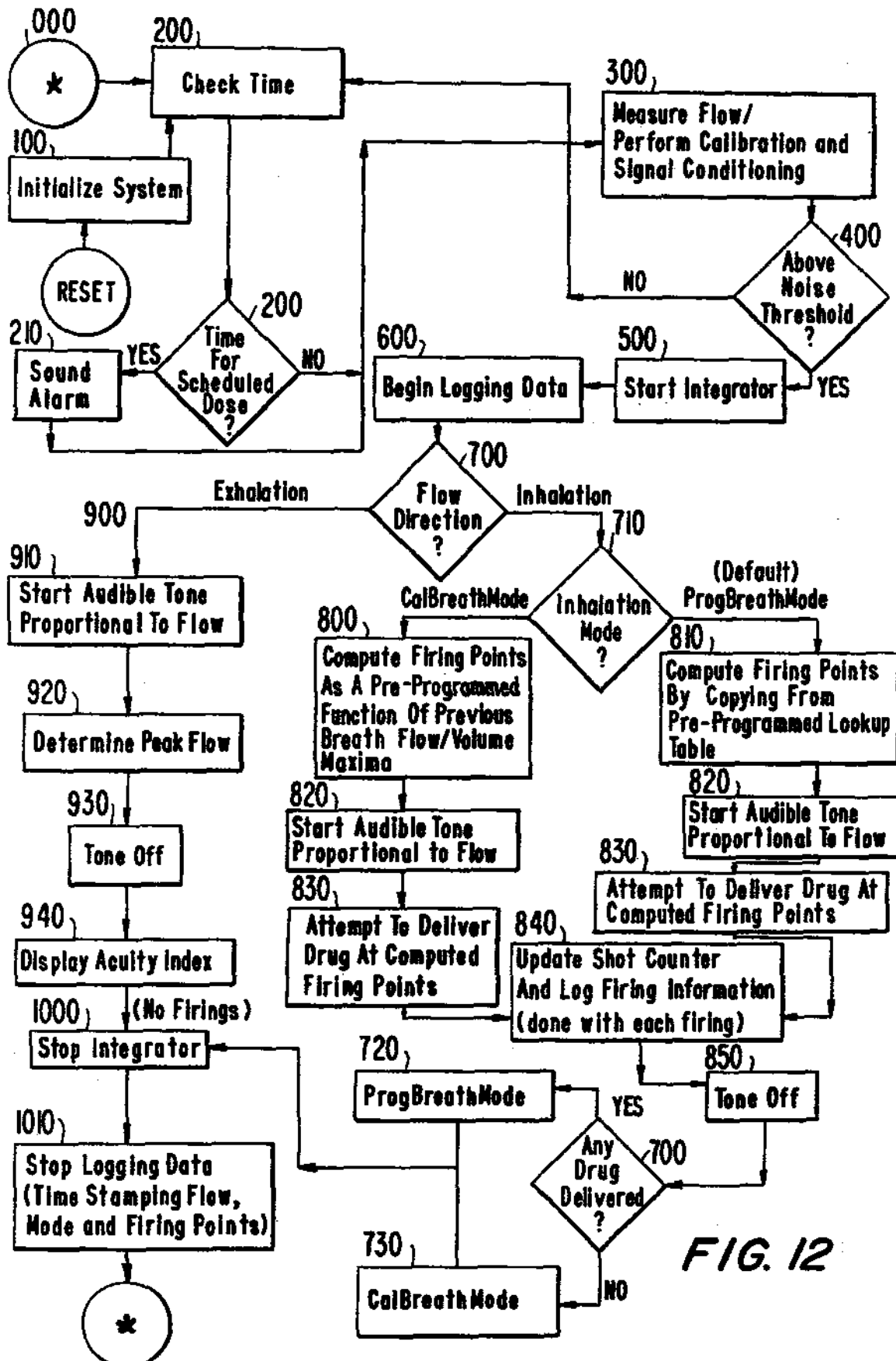
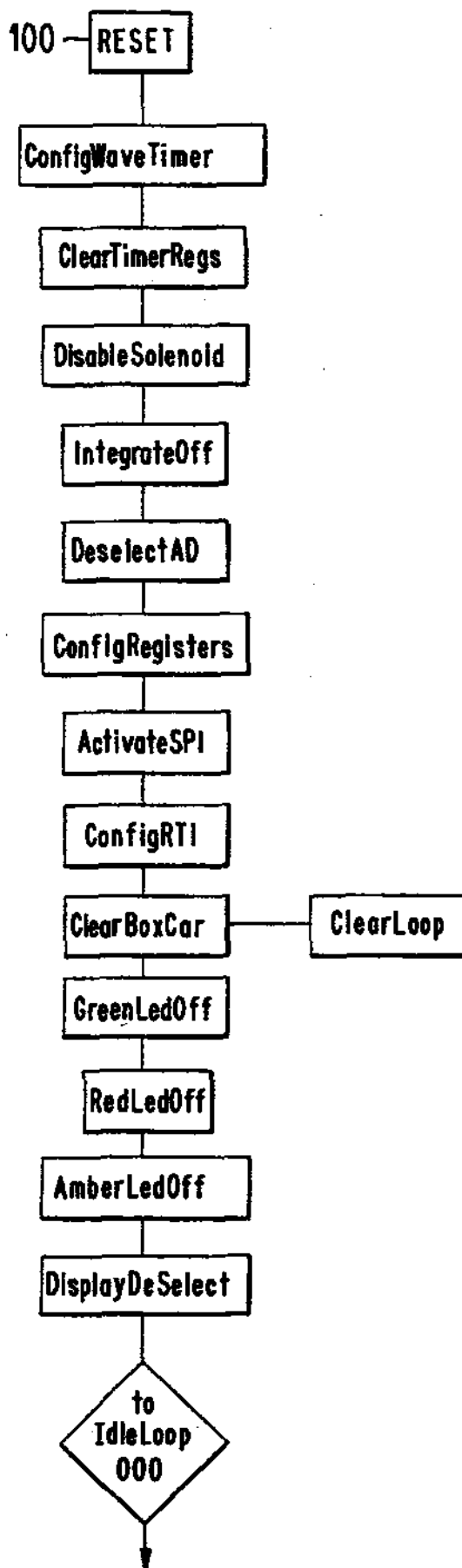


FIG. II



**FIG. 13A**

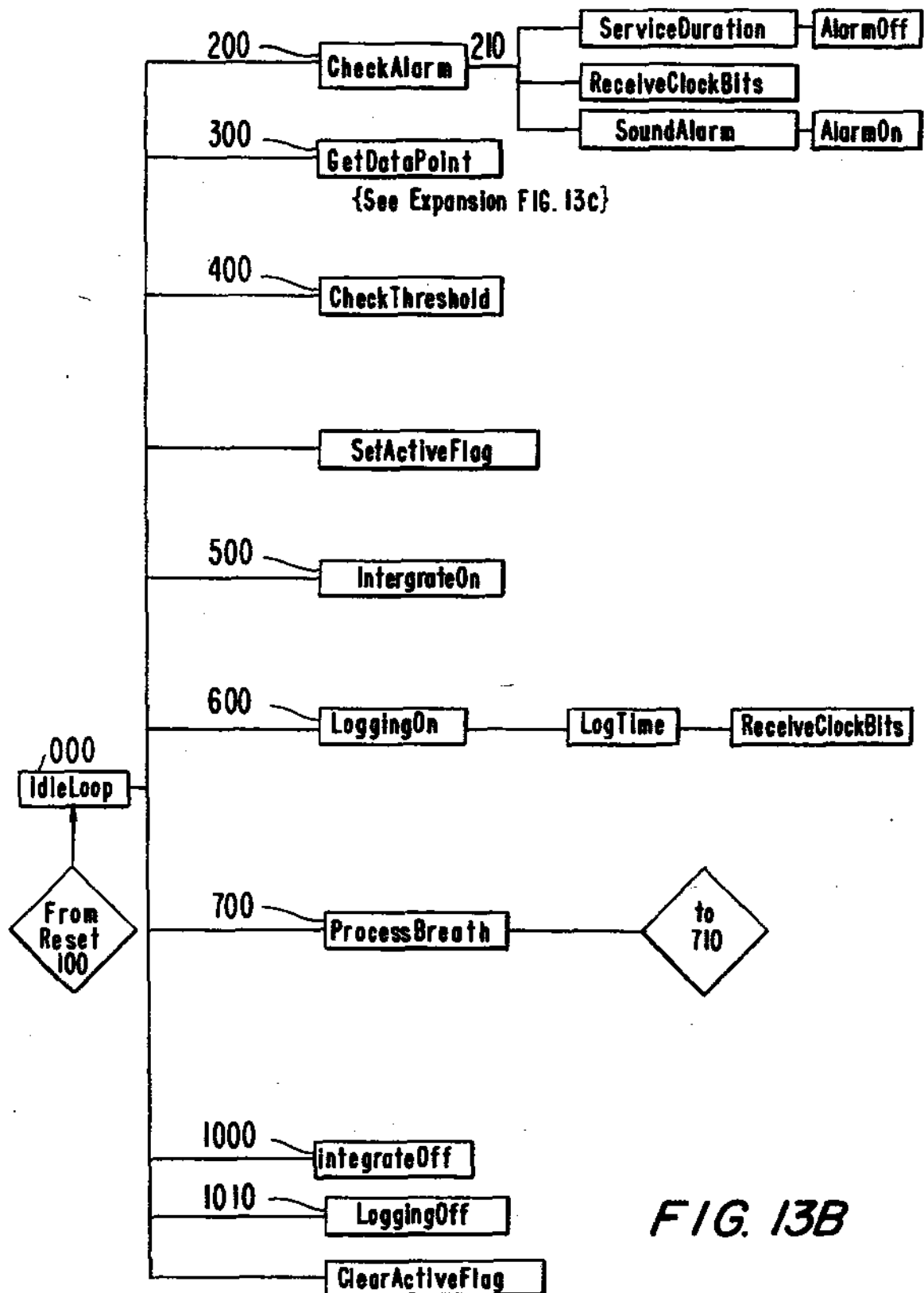


FIG. 13B

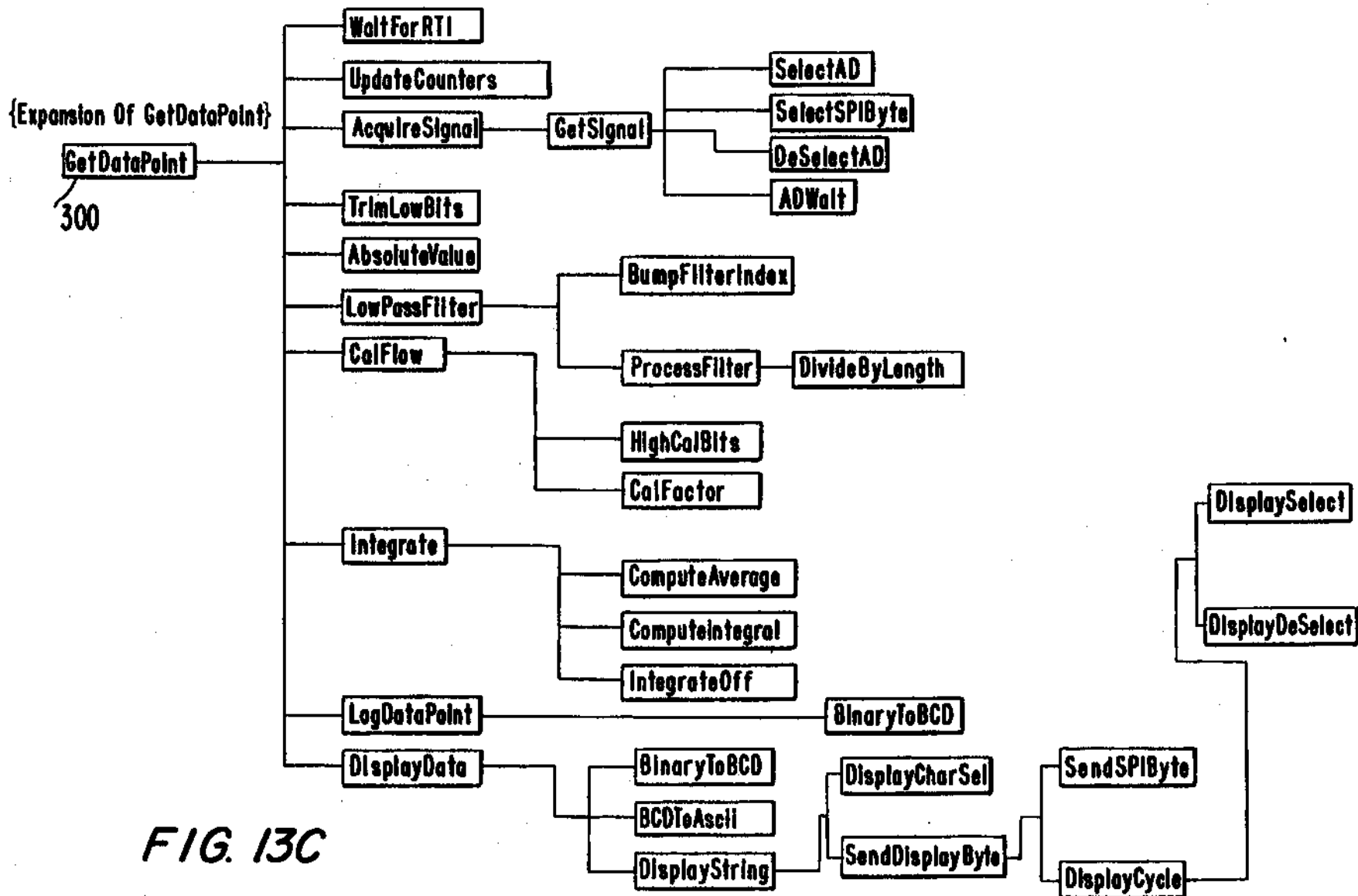


FIG. 13C

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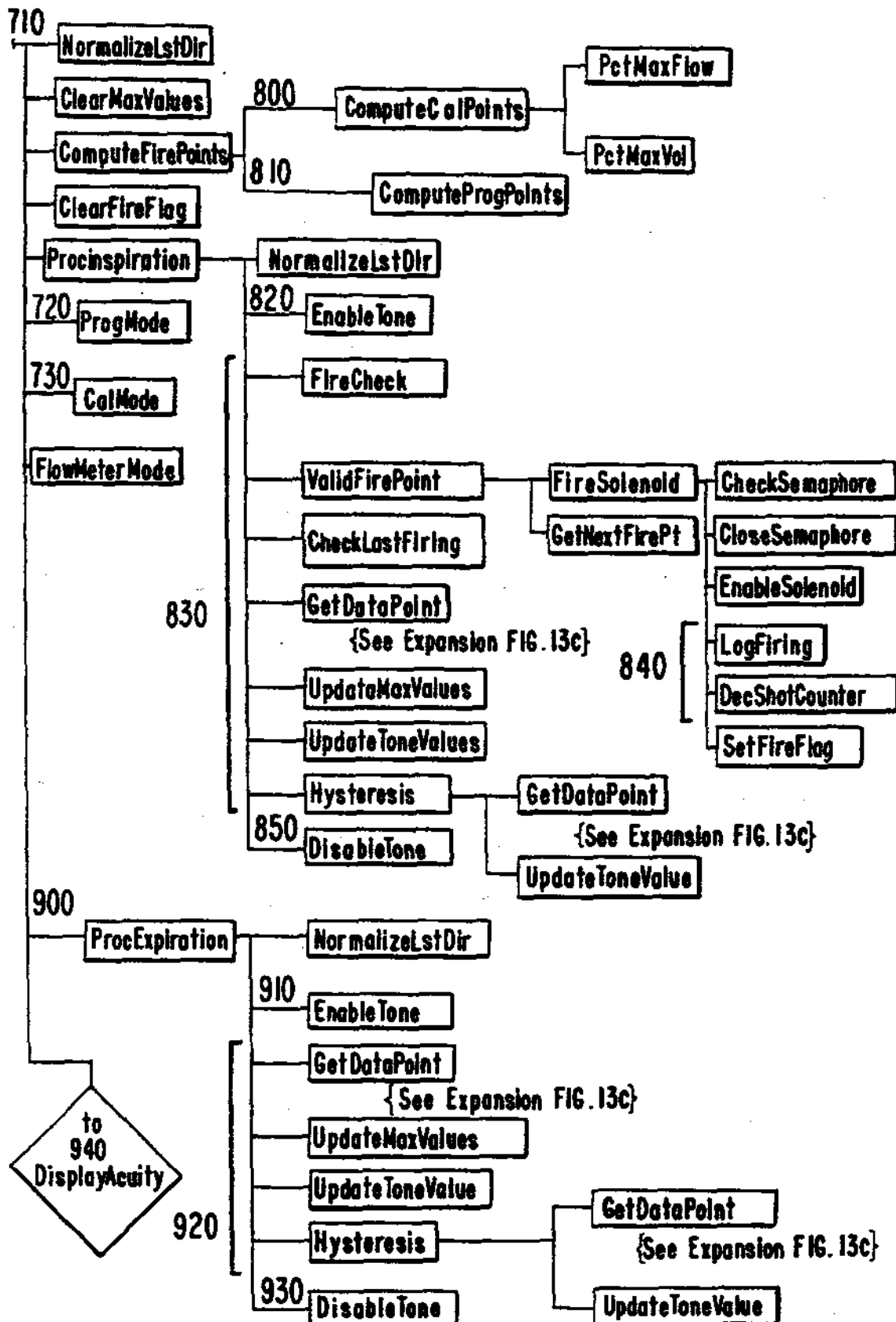


FIG. 13D

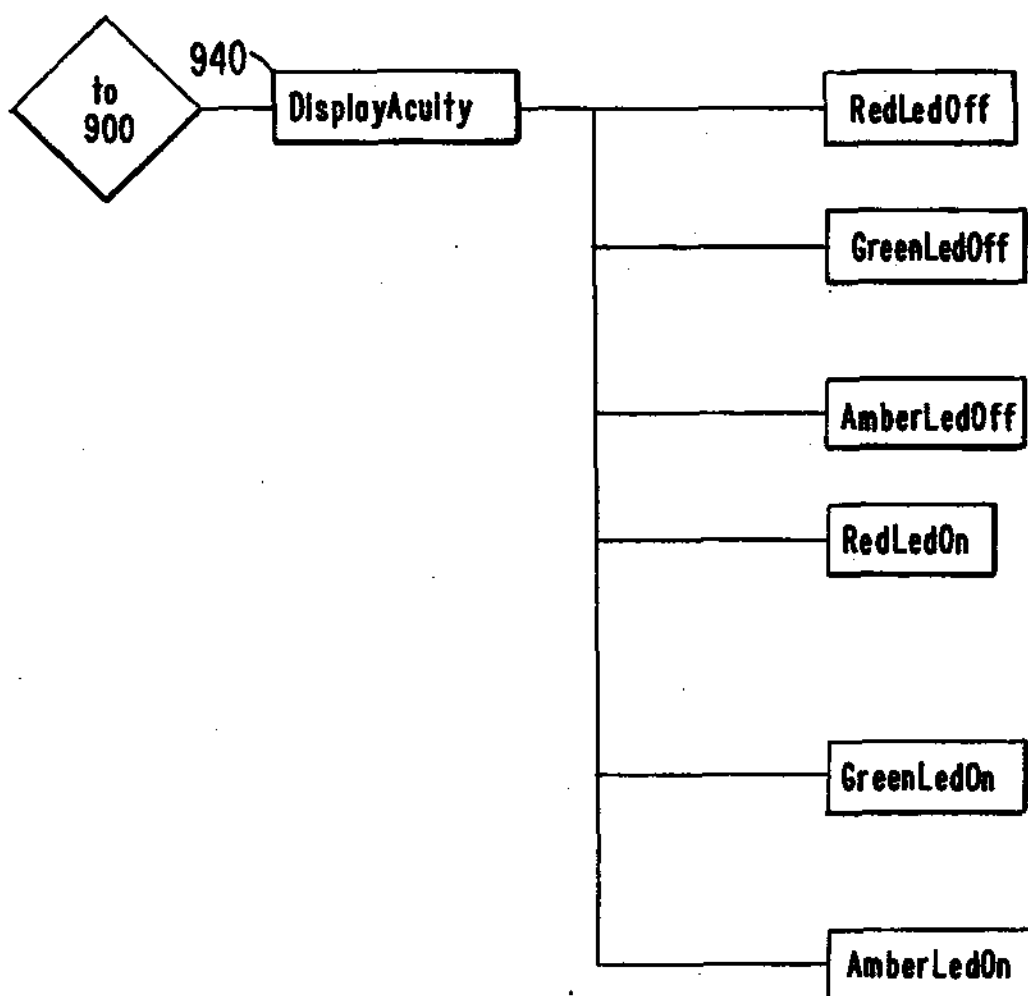
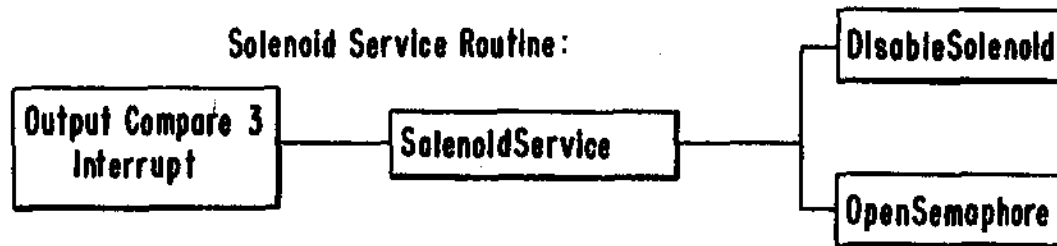


FIG. 13E

Interrupt Service Routines



Clock/Calendar Initialization Routine



FIG. 13F

5,404,871

1

DELIVERY OF AEROSOL MEDICATIONS FOR INSPIRATION

This invention relates to delivery of aerosolized materials and specifically to improvements in the delivery of aerosolized medications for inspiration by patients for more effective therapeutic and diagnostic purposes.

BACKGROUND OF THE INVENTION

Devices for the delivery of aerosol medications for inspiration are known. One such device is a metered dose inhaler which delivers the same dosage of medication to the patient upon each actuation of the device. Metered dose inhalers typically include a canister containing a reservoir of medication and propellant under pressure and a fixed volume metered dose chamber. The canister is inserted into a receptacle in a body or base having a mouthpiece or nosepiece for delivering medication to the patient. The patient uses the device by manually pressing the canister into the body to close a filling valve and capture a metered dose of medication inside the chamber and to open a release valve which releases the captured, fixed volume of medication in the dose chamber to the atmosphere as an aerosol mist. Simultaneously, the patient inhales through the mouthpiece to entrain the mist into the airway. The patient then releases the canister so that the release valve closes and the filling valve opens to refill the dose chamber for the next administration of medication. See, for example, U.S. Pat. No. 4,896,832 and a product available from 3M Healthcare known as Aerosol Sheathed Actuator and Cap.

A major problem with metered dose inhalers is that the patient frequently actuates the device at the incorrect time during inspiratory flow to obtain the benefits of the intended drug therapy, e.g., too early or too late in the flow cycle or during expiration.

Another device is the breath actuated metered dose inhaler which operates to provide automatically a metered dose in response to the patient's inspiratory effort. One style of breath actuated device releases a dose when the inspiratory effort moves a mechanical lever to trigger the release valve. Another style releases the dose when the detected flow rises above a preset threshold, as detected by a hot wire anemometer. See, for example, U.S. Pat. Nos. 3,187,748; 3,565,070; 3,814,297; 3,826,413; 4,592,348; 4,648,393; 4,803,978.

Existing breath actuated devices have not, however, been entirely successful in overcoming the problem of timing drug delivery to the patient's inspiration. For one thing, breath activated drug delivery is triggered on crossing a fixed threshold inspiratory effort. Thus, an inspiration effort may be sufficient to release a metered dose, but the inspiratory flow following the release may not be sufficient to cause the aerosol medication to pass into the desired portion of the patient's airways. Another problem exists with some patients whose inspiratory effort may not be sufficient to rise above the threshold to trigger the release valve at all.

Other attempts have been made to solve the patient inspiration synchronization problem. U.S. Pat. No. 4,484,577 refers to releasing a dosage of drug into a bag for the patient to inhale and using a bidirectional reed whistle to indicate to the patient the maximum rate of inhalation for desired delivery of the drug or a flow restrictor to prevent the patient from inhaling too rapidly. U.S. Pat. No. 3,991,304 refers to using biofeedback

2

techniques to train the patient to adopt a breathing pattern including tidal volume, respiratory frequency, and inspiration and expiration times for efficient delivery of aerosols for inhalation therapy. U.S. Pat. No. 4,677,975 refers to detecting the beginning of inspiration, and using audible signals and preselected time delays which are gated on the detection of inspiratory flow to indicate to the patient when to inspire and expire, and delivering inhalable material to the mouthpiece a selected time after the detected onset of flow. U.S. Pat. No. 4,932,402 refers to modifying continuous gas flow devices by determining the patient's breathing cycle rate over a period of several breaths and providing pulses of oxygen or other medicinal gases for inhalation during inspiration such that the volume of gas delivered changes in response to changes in the patient's breathing rate. However, these devices also suffer from improper operation by patients who do not conform their breathing to the instructed breathing pattern or whose inspiratory flow does not provide adequate delivery of the medication.

It also is noted that devices exist to deliver dry powdered drugs to the patient's airways as in U.S. Pat. No. 4,527,769 and to deliver an aerosol by heating a solid aerosol precursor material as in U.S. Pat. No. 4,922,901. These devices typically operate to deliver the drug during the early stages of the patient's inspiration by relying on the patient's inspiratory flow to draw the drug out of the reservoir into the airway or to actuate a heating element to vaporize the solid aerosol precursor. However, these devices are subject to improper and variable delivery of the powdered drug or vaporized aerosol, depending on the variations of the patient's inspiration effort and any sustained flow.

A problem with metered dose inhalers is that patients' abilities to use or to be trained to use the device properly vary widely. Thus, whether or not the device is breath actuated, patients may inspire too little medication. Further, in the event that a patient administers an additional dose to compensate for an actual or perceived partial prior dose, too much medication may be inspired. This produces inconsistent and hence inadequate therapy.

Another problem with metered dose inhalers is that they always provide a fixed, uniform dose of medication which is delivered at the time the device is activated. However, in many inhalation therapy programs a gradual reduction in the dose would be more appropriate for the treating the patient's gradually improved condition. In addition, delivery of the dose at different points in the inspiratory flow cycle may be more efficacious than delivery of a single bolus.

It is known that the therapeutic effect of an inhaled drug is affected by where it is deposited in the lungs. The human respiratory tract branches about twenty-three times. The resulting bronchial tree thus contains airway segments having lengths that vary from 12 cm to 0.05 cm, and corresponding diameters that vary from 1.80 cm to 0.041 cm, for an average adult. The smallest airways give rise to the alveoli, the air sacs in contact with the blood stream where gas exchange occurs.

The bronchial tree can be broadly divided into two groups, small airway populations and large airway populations. Specific drugs have different optimal delivery sites within the bronchial tree. For example, bronchodilators used for treating asthma should be deposited in both large and small airways, whereas drugs intended for systemic absorption such as peptides, e.g., insulin,

should be deposited as far in the peripheral large airways of the lung as possible.

Studies in Bryon (ed.), *Respiratory Drug Delivery*, CRC Press, Inc. (1990); Newman et al., *Thorax* 1981, 36:52-55; Newman et al. *Thorax*, 1980, 35:234; Newman et al., *Eur. J. Respir. Dis.*, 1981, 62:3-21; and Newman et al., *Am. Rev. Respir. Dis.*, 1981, 124:317-320 indicate that during a single breath of an aerosol compound, only about ten percent of the total aerosol material presented is deposited into the lungs and that the location of deposition in the lung depends upon 1) breath parameters such as volume of inspiration, inspiratory flow rate, inspiratory pause prior to expiration, the lung volume at the time the bolus of medication is administered, and expiratory flow rate, 2) the size, shape and density of the aerosol particles (i.e., the medicinal compound, any carrier, and propellant), and 3) the physiological characteristics of the patient.

Bryon reports that if the deposition fraction is plotted as a function of the airway generation number (See Table I), a bimodal distribution is obtained as illustrated in FIG. 1. The first peak is produced because inertial impact is maximal in the larger airways where airways velocity is highest. This effect is not seen in medium sized airways where velocity is lower and airway size is too large to permit deposition by sedimentation under gravity. The second peak appears in the more distal and smaller airways where velocity is slowest and deposition by sedimentation occurs.

TABLE I

Airway Lengths and Diameters from the Morphological Model of Weibel (Bryon, <i>Respiratory Drug Delivery</i> , CRC Press (1990))		
Generation	Length (cm)	Diameter (mm)
0	12.000	1.800
1	4.760	1.220
2	1.900	0.830
3	0.760	0.560
4	1.270	0.450
5	1.070	0.350
6	0.900	0.280
7	0.760	0.230
8	0.640	0.186
9	0.540	0.154
10	0.460	0.130
11	0.390	0.109
12	0.330	0.095
13	0.270	0.082
14	0.230	0.074
15	0.200	0.066
16	1.165	0.060
17	0.141	0.054
18	0.117	0.050
19	0.099	0.047
20	0.083	0.045
21	0.070	0.043
22	0.059	0.041
23	0.050	0.041

The Bryon and Newman studies also suggest that the modal distribution pattern, and thus the relative location of deposited medication, can be modified by changing those parameters.

The Newman references refer to measuring inspired air with a pneumotachograph to obtain a flow rate signal, which is integrated by a computer to determine lung capacity. A determined lung capacity, as a percent of vital capacity, is used as a threshold to actuate a solenoid to depress the canister of a metered dose inhaler on the inspiration of the predetermined lung volume.

A problem with existing metered dose inhalers, whether or not breath actuated, is that they are factory preset for a given particle size distribution and that distribution cannot be varied. Thus, those devices are not capable of selecting a maximum desired respirable fraction of the aerosol mist that is suitable for a desired location of delivery of the medication. Further, metered dose devices, and in particular breath actuated devices, cannot deliver a metered dose having a selectable respirable fraction in response to an identified point in the patient's inspiratory flow to provide for selective deposition of the medication in selected areas of the lungs.

Devices for controlling particle size of an aerosol are known. U.S. Pat. No. 4,790,305 refers to controlling the particle size of a metered dose of aerosol for delivery to the walls of small bronchi and bronchioles by using a first container into which the medication is delivered prior to inspiration by the patient and a second collapsible container which contains a fixed volume of air to be inspired immediately prior to inspiration of the metered dose of medication, and flow control orifices to control the flow rate. U.S. Pat. No. 4,926,852 refers to metering a dose of medication into a flow-through chamber that has orifices to limit the flow rate to control particle size. U.S. Pat. No. 4,677,975 refers to a nebulizer device that uses baffles to remove from an aerosol particles above a selected size which particles may be returned to the nebulizer for reuse. U.S. Pat. No. 3,658,059 refers to a baffle that changes the size of an aperture in the passage of the suspension being inhaled to select the quantity and size of suspended particles delivered. A problem with these devices is that they process the aerosol after it is generated and thus are inefficient and wasteful.

It is well known that pulmonary functions, such as forced expiratory volume in one second, forced vital capacity, and peak expiratory flow rate, can be measured based on measured flow rates and used both to diagnose the existence of medical conditions, and to ascertain the efficacy of a drug therapy program. See for example, U.S. Pat. Nos. 3,991,304 and 4,852,582 and the Newman references discussed above. Heretofore, these tests have been performed using available spirometers. U.S. Pat. No. 4,852,582 also refers to using a peak flow rate meter to measure changes in peak flow rate before and after administration of a bronchodilator. The results of such tests before and after administration of several different medications are used to evaluate the efficacy of the medications, which are then used and compared to various laboratory standard or predetermined data to make a diagnosis and prescription for treatment of the patient's condition.

A problem with the foregoing pulmonary function test devices is that they are complicated for most patients to perform. Another problem is that the test data must be examined and interpreted by a trained medical practitioner to be meaningful. Another problem is that they do not provide adequately for altering the dosage of the medication administered in a single patient during the course of therapy, or from patient to patient, using the same delivery device for generating an aerosol of the same or different medications.

SUMMARY OF THE INVENTION

It is, therefore, an object of this invention to provide improved apparatus, systems, and methods for delivering aerosol compounds for inspiration by a patient.

It is another object of this invention to provide improved apparatus, systems, and methods for delivering

for inspiration an aerosol having a particle size distribution favorable for selective deposition into desired locations in a patient's pulmonary system. It is another object to release a controlled amount of aerosol in one or more pulses having a selected pulse size, shape, and frequency and number of pulses to produce a selected particle size distribution. It is another object to provide a variably actuated valve mechanism having an open state and a closed state for controlling the medication pulse size, shape, and frequency, to produce a pulse train having a selected particle size distribution at a selected point or a series of selected points in the patient's inspiratory flow and, further, to produce a pulse train so that the particle size distribution delivered at different points in the flow may be different.

It is another object of the invention to deliver aerosolized compounds in response to a measure of a patient's breathing pattern during inspiration. It is another object to select the optimal point or points for release of one or more pulses of medication based on an analysis of the patient's inspiratory flow in a first detected flow and to release the medication on the occurrence of the determined point or points during a subsequently detected inspiratory breath.

It is another object to select the location of deposition of the medication in the patient's airway by selecting the optimal point or points in the inspiratory flow to achieve such deposition. It is another object to deposit selectively the medication based on a selected optimal flow point and a selected pulse train to obtain a desired respirable fraction for such deposition. It is another object to prompt the patient to hold his or her breath for an optimal period of time at the end of inspiration to optimize delivery of the aerosolized compound being administered.

It is another object of the invention to release automatically a controlled amount of medication when the patient's detected inspiratory flow exceeds a preselected or default delivery threshold, and, if the first detected flow does not exceed (or satisfy) the default delivery threshold, to determine a new delivery threshold based on a detected flow maxima parameter of the previously detected inspiratory flow not exceeding the prior delivery threshold and to release a controlled amount of medication when a subsequently detected flow exceeds the new determined delivery threshold. The determined threshold is thus recursively determined for each detected inspiratory flow not exceeding the previously established delivery threshold, whether that threshold is the preselected default triggering threshold or a subsequently determined threshold.

It is another object of this invention to provide improved apparatus, systems, and methods for delivering aerosolized compounds for inspiration by a patient by incorporating a measure of a patient's pulmonary function to provide for varying the dosage or controlled amount of the aerosolized compound delivered for inspiration by the patient in response to detected changes in the patient's pulmonary function during a course of therapy directed to improving pulmonary function.

It is another object to provide improved apparatus, systems, and methods for delivering aerosol compounds for inspiration by a patient by incorporating a measure of a patient's pulmonary function and an acuity display of that function to the patient, for example, to provide for alerting the patient whether the patient's determined function indicates whether the patient should continue

the inhalation drug therapy program or seek immediate medical attention.

It is another object of the present invention to provide a programmable, durable variable dose inhaler whereby the medication being administered can be selected and the inhaler can be programmed to provide for efficacious delivery of the selected medication to a given patient. It is another object to provide such a device with a library of information regarding medications to be administered and their respective administration protocols. It is another object to provide an improved inhaler with audible, visual or audiovisual feedback for prompting the patient to obtain a suitable breathing pattern for delivering a selected medication at an appropriate time based on the patient's detected inspiratory flow and, optionally, for measuring a pulmonary function. It is another object to provide feedback for prompting the patient's breathing pattern in response to previously measured pulmonary or flow parameters for automatic administration of the selected medication. It is another object to provide a visual display of the adequacy of a dosage delivered and other parameters regarding the course of therapy, such as time of next dose to be administered. It is another object to provide the medical examiner with a history log of drug administration and points of drug delivery for evaluation.

A further object of the present invention is to provide a hand held microprocessor controlled inhaler device for use in outpatient aerosol drug therapy that is capable of autonomously modifying the initial therapy program based on detected progressive changes in the patient's breath flow and corresponding pulmonary functions. It is another object to provide for communications between the device and a remote station for remote reprogramming of the microprocessor controlled device for external modification of the therapy or for transmitting historical log data for evaluation.

It is another object to provide a disposable mouthpiece containing a nozzle for dispensing medication and a flow rate sensor located in the flow path to detect flow so that it does not interfere with generation of an aerosol for inspiration by a patient.

The present invention increases the effectiveness and utility of devices for delivering aerosolized medications and overcomes the problems of the prior known devices. Broadly, the invention concerns methods and apparatus for achieving the above objectives based on detecting the patient's inspiratory flow and releasing one or more pulses of an aerosol medication respectively at one or more identified points in the detected flow to provide an efficacious delivery of a selected amount of medication.

The following terms are used in describing the present invention. The term "delivery point" refers to a point in the detected inspiratory flow at which an amount of aerosol is to be delivered. The term "amount of aerosol" refers to the amount released in response to the occurrence of a delivery point. The amount may be either a single pulse, or a preselected number of pulses, e.g., four pulses having the same shape and frequency. The term "delivery schedule" refers to one or more delivery points in the detected inspiratory flow such that a full dosage of aerosol is delivered in accordance with the delivery schedule. Thus, a delivery schedule that includes only one delivery point will deliver an amount of aerosol in response to the occurrence of that point in the detected inspiratory flow that corresponds

FIG. 10 is a schematic diagram of the solenoid control module of FIG. 4;

FIG. 11 is a schematic diagram of the speaker module of FIG. 4;

FIG. 12 is a flow chart of the software of a preferred embodiment of the device of FIG. 4 in accordance with the present invention; and

FIGS. 13A-13F are collectively a flow chart of the subroutine calling chain of the software embodiment of FIG. 12 and the software appendix.

DETAILED DESCRIPTION OF THE INVENTION

Referring to FIGS. 2A, 2B, and 3, one embodiment of the present invention includes base 3100, canister 3200, flow sensor 3300, solenoid valve 3150, aerosol delivery system 3130, mouthpiece 3110, and control circuits 3400 (circuits 3400 not shown in FIG. 2A). Canister 3200 preferably contains a medication under pressure and has a valve 3210 for releasing medication. Base 3100 includes a receptacle 3120 for receiving canister 3200, a valve seat 3122 for receiving canister valve 3210, and means 3125 for retaining canister 3200 in receptacle 3120 as described herein. Means 3125 is preferably a threaded cap that screws into (FIG. 2b) or about (FIG. 2A) the open end of receptacle 3120 so that an inserted canister 3200 is fully seated in receptacle 3120 in a stationary position. In the fully seated position, canister valve 3210 is depressed open and the contents of canister 3200 are thus in communication with aerosol delivery system 3130.

Means 3125 may include alternate structures for locking canister 3200 in the fully seated position, for example, a locking hinged lid or a conventional bayonet mount connection wherein the canister body has one or more protrusions that mesh with one or more receptacles in receptacle 3120 when the canister is fully inserted and rotated in receptacle 3120.

Canister 3200 is preferably a conventional canister containing the medication to be delivered and a suitable propellant or carrier for the medication and having valve 3210 for controlling the release of medication when valve 3210 is depressed and thus opened. Such canisters 3200 are commercially available from a variety of sources and are well known in the art. One such canister is model No. C-128-S available from Prespart Co. and one suitable valve for that canister is a straight valve model no. BK-295, available from BESPAC, King's Lynn, England.

Aerosol delivery system 3130 operates under the control of control circuits 3400 and provides one or more pulses of medication from canister 3200 to airflow path 3140 and mouthpiece 3110 by selective control of solenoid valve 3150. System 3130 includes valve seat 3122, inlet channel 3124, solenoid valve 3150, outlet channel 3154, and aerosol nozzle 3160. Inlet channel 3124 forms a gas communication path between canister 3200 and solenoid valve 3150 for passing the pressurized contents of canister 3200 to valve 3150. Outlet channel 3154 forms a gas communication path from valve 3150 to nozzle 3160, for passing the pressurized contents of canister 3200 to nozzle 3160 to deliver an aerosol into air flow path 3140.

When solenoid valve 3150 is inactive or closed, inlet channel 3124 does not pass gas therethrough. Channel 3124 thus will equilibrate with the contents of canister 3200. Similarly, outlet channel 3154 does not pass gas therethrough and will equilibrate with the atmosphere.

When valve 3150 is actuated or open, channels 3124 and 3154 are in open communication and the contents of canister 3200 are released to the atmosphere through nozzle 3160 to form an aerosol. Solenoid valve 3150 thus controls the delivery of the contents of canister 3200 to the patient as described further herein.

Referring to FIG. 2A, channel 3124 is tooled in manifold 3123 and manifold 3155, which respectively interface receptacle 3120 and solenoid 3150, and channel 3154 is tooled in manifold 3155 for interfacing solenoid 3150 and nozzle 3160. The use of manifolds provides for removable interconnections for repair, cleaning or replacement of parts of base 3100.

Air flow path 3140 is formed of a tube 3141, preferably having a flattened cylindrical cross section, and includes a mouthpiece 3110 at mouth end 3142 and flow sensor 3300 at back end 3144. Interposed between mouth end 3142 and back end 3144 is a projection 3165 which contains nozzle 3160 and is secured to the wall of air flow path 3140. Projection 3165 is provided with a dimension that does not interfere with flow through path 3140 and preferably extends diametrically across flow path 3140 so that nozzle 3160 is directed to release an aerosol into and in longitudinal alignment with air flow path 3140 for inspiration by the patient. Projection 3165 is preferably made of the same material as tube 3141 forming flow path 3140, e.g., an acrylic material, and more preferably is molded as a part of tube 3141. Nozzle 3160 is preferably provided with a configuration that facilitates aerosol generation and dispersion appropriate for the tube dimensions.

Tube 3141 preferably provides mouthpiece 3110 with a cylindrical cross section preferably larger than the aerosol plume delivery into the patient's mouth. Tube 3141 need not have a uniform cross section, but desirably has minimal pressure drop there across (excluding any pressure drop across sensor 3300). Alternate embodiments for the cross section of mouth end 3142 may include circular, oval or flattened oval cross sections or other configurations developed to provide a good seal between the patient's mouth and flow path 3140 so that the patient's inspiratory and expiratory flow passes substantially through tube 3141 along path 3140.

Flow sensor 3300 may be any sensor that provides a measure of flow at a rate of from about 0 to about 800 liters per minute. Flow sensor 3300 is located in flow path 3140 where it will not interfere with the delivery of aerosol to the patient, yet is able to measure both inspiratory and expiratory flow. In the preferred embodiment, sensor 3300 includes a flow resistor device that provides laminar air flow across sensor 3300, comprising three screens, 3304, 3305, and 3306, and two pressure ports 3302 and 3303. Associated with sensor 3300 are a conventional pressure differential transducer 3301 and circuits for obtaining a flow measurement (see FIGS. 4 and 6, transducer 3301 is illustrated in FIG. 2B for reference). Screens 3304, 3305 and 3306 are oriented perpendicular to air flow path 3140, spaced apart $\frac{1}{4}$ " in parallel and secured to the inside of tube 3141 so that they extend across the cross sectional area of path 3140. Referring to FIG. 2A, tube 3141 is assembled by gluing together, in axial alignment, mouth tube section 3110, screen 3306, tube section 3111, screen 3305, tube section 3112, screen 3304, and end tube section 3144 whereby the lengths of tube sections 3111 and 3112 define the spacing between the screens.

Screen 3305 is a resistor screen across which a differential pressure is measured at ports 3302 and 3303 to

obtain a measure of the flow rate. Screens 3304 and 3306 provide a laminar air flow across screen 3305 and through sensor 3300 which is suitable for obtaining air flow measurements. Port 3302 is located between screens 3306 and 3305, and port 3303 is located between screens 3305 and 3304. Referring to FIG. 2B, ports 3302 and 3303 are respectively connected to transducer 3301 by conventional flexible tubes 3307 and 3308 having about a 3 mm inner diameter and provide the differential pressures developed across resistive screen 3305 to transducer 3301. The differential pressures, preferably in the range of plus or minus 10 cm of water, are then used to provide a voltage proportional to flow through path 3140, and the sign of the voltage determines the direction of flow. One such preferred differential flow transducer 3301 is model No. NPH-8-2.5DH, commercially available from NOVASENSOR of Fremont, Calif. The flow through pathway 3140 may be sampled at 60 Hz to obtain the flow rate measurements.

Other forms of such a sensor 3300 may be other forms of a pneumotachograph, e.g., a temperature compensated device, or a thermal wire air flow measurement system. A pneumotachograph is a known sensor having a pneumatic resistor interposed in an air flow, such as a resistor screen, that maintains a laminar air flow having a pressure drop across the structure. The pressure drop is measured and can be directly related to air flow rates across the structure by the pneumatic equivalent of Ohm's law. Thus, once the sensor is calibrated, the air flow rate can be accurately determined based on the measured pressure drop for any air flowing across the structure within the operating range of the sensor.

In an alternate embodiment (not shown), a suitable differential pressure flow sensor could include, for example, a venturi device or a flow resistive screen not characterized by laminar flow, provided that the raw differential pressure measurement obtained across such a venturi device or the flow resistor is calibrated to account for the non-linearity of the air flow path so that the calibrated flow data correspond to data from a linear flow path.

In the preferred embodiment, flow path 3140, including mouthpiece 3110, protrusion 3165, and sensor 3300 (optionally not including transducer 3301) may be removable from body 3100 so that it may comprise a disposable part. A conventional detachable connection, not shown, may be provided. Accordingly, means for interconnecting channel 3154 to valve 3150, such as a male-female snap connection, may be incorporated into the design. Use of a disposable airway is desirable because debris will accumulate on the part so that it can be cleaned or a new mouthpiece provided. Similarly, if a filter is provided (not shown), that filter may be separately removable from the part for replacement.

Referring to FIGS. 2, 3, 4, and 5, control electronics 3400 for an embodiment of the present invention are shown. Electronics 3400 include a microprocessor 2000, an external memory subsystem 2100, a decoder circuit 2020, a latch device 2030, a reset circuit 2040, a clock oscillator 2010, a data acquisition subsystem 2200, three LED annunciator subsystems 2300, 2400 and 2500, a solenoid actuator subsystem 2600, an audio speaker subsystem 2700, and a character display subsystem 2800. The discrete components of electronics 3400 are conventional parts having input and output pins which are configured as illustrated in FIGS. 4-11 and described herein, which connections are made in accor-

dance with the instructions provided by the device manufacturers, unless otherwise stated.

Use of CMOS technology for electronics 3400 is preferred because of the low power consumption of such devices. This permits the use of a battery powered, portable, hand-held device for patient use having a size that compares favorably to existing metered dose inhaler devices.

Microprocessor 2000 is provided with suitable software programming that controls the operation of the device. One embodiment of such software is set forth as a software appendix to this specification and is discussed below.

Optionally, electronics 3400 may include a voltage converter and an associated output port for converting the digital information to a voltage format compatible for communicating with another microprocessor device, for example, an RS232 port or a facsimile machine (not shown). Further, as discussed in detail below, electronics 3400 may include means for reading a canister code for identifying the contents of the medication to be administered and selecting the device administration protocol for the identified medication (not shown).

Referring to FIG. 4, microprocessor 2000 may be any software controlled device suitable for operating the data acquisition and determination functions and for controlling the operation of solenoid valve 3150 to release the selected number of pulses of medication at the desired points in the patient's inspiratory flow in accordance with the preferred embodiment of the invention. One suitable device for microprocessor 2000 is model no. MC68HC11A1, available from Motorola, Inc., Microcontroller Division, Austin, Tex., the use of which is described herein.

Microprocessor 2000 is preferably configured to run in an expanded multiplexed mode through connection of lines MODA and MODB at pins 2 and 3 to logic one, a reference voltage Vcc of +5 volt fed across a 10 K Ω resistor. Latch device 2030 is preferably an 8 bit device that demultiplexes the address and data information transmitted along port c at pins 9-16 of microprocessor 2000 and allows addressing of the address space of memory subsystem 2100. Latch 2030 is preferably model 74HC373, available from National Semiconductor, Santa Clara, Calif.

Memory subsystem 2100 preferably has a 64K byte address space and includes two 32K byte non-volatile CMOS RAM devices 2110 and 2120, each containing an internal lithium battery. Preferably, RAM devices 2110 and 2120 each contain a non-volatile clock/calendar that is settable and accessible under software control by microprocessor 2000. In the preferred embodiment, only the clock/calendar of device 2110 is used. Non-volatile RAM devices 2110 and 2120 thus provide for maintaining a date and time record of the data acquired and the operation of the device for subsequent review and evaluation by appropriate medical practitioners. This will enable evaluation of the performance of the device for the delivery of medication and the efficacy of the drug therapy program for the patient, even in the event of general power loss of electronic control circuits 3400. The clock/calendar feature also can be used to perform the alarm clock feature to indicate to the patient that a dose is to be administered, for example, by reviewing a list of scheduled dosing times. Appropriate RAM devices 2110 and 2120 are preferably models DS1244Y, available from Dallas Semiconductor, Dallas, Tex.

The 64K byte address space of memory subsystem 2100 may be continuously addressed in the following manner. Signal AS at pin 4 of microprocessor 2000 causes the low 8 bits of a 16 bit address to be latched from port c at pins 9-16 of microprocessor 2000 into pins 2, 4, 7, 8, 13, 14, 17, and 18 of latch 2030. The latching of these address bits into latch 2030 allows 8 bits of data from port c, the high address bits from port b (pins 35-42 of microprocessor 2000) and the low 8 address bits from the output at pins 2, 5, 6, 9, 12, 15, 16, and 19 of latch 2030 to be available simultaneously.

Decoder device 2020 is used to decode the write enable WE/, output enable OE/, and chip enable CE/ control lines at pins 27, 22, and 20 respectively of each of RAMs 2110 and 2120. A suitable decoder device 2020 is model 74HC139, available from National Semiconductor, Santa Clara, Calif. Address line A15 from line PB7 at pin 35 of microprocessor 2000, is input to line 1A at pin 2 of decoder 2020 and is used to determine which 32K byte RAM bank to select for each memory access. Valid WRITE/, READ/, CE/1, and CE/2 signals respectively coming from pins 10, 9, 6, and 7 of decoder 2020 are all active low and are valid only when the signal E from pin 5 of microprocessor 2000 is raised active high. This procedure ensures that memory subsystem 2100 will be accessed only during valid memory references.

Clock 2010 provides a clock input for microprocessor 2000. Preferably, clock 2010 is a CMOS oscillator having a frequency of 8.0 MHz. A suitable device for clock 2010 is model MX045, available from CTS Inc., Japan.

Referring to FIGS. 4 and 5, reset circuit 2040 provides a power-on reset function. Reset circuit 2040 includes a reference voltage Vcc, resistor 2041, capacitor 2042 and switch 2043. When the system is turned on, a transient pulse from ground to voltage Vcc is generated. Vcc is preferably +5 volts, resistor 2041 is preferably 1 K Ω , and capacitor 2042 is preferably 2.2 microfarads. Resistor 2041 thus presents a logic high signal to the non-grounding lead of capacitor 2042 when power is applied to the system. However, the potential across capacitor 2042 does not change instantaneously and a ground potential is presented to the RESET/line at pin 17 of microprocessor 2000 until capacitor 2042 charges. This provides for a reset of microprocessor 2000, its software routines, and the electronic system of the device. A manual reset may be obtained at an arbitrary time by closing switch 2043. This provides for discharging capacitor 2042 to obtain a transient ground pulse for resetting microprocessor 2000.

Referring to FIGS. 4-11, microprocessor 2000 is configured to be connected to and control data acquisition subsystem 2200, LED annunciator modules 2300, 2400, and 2500, solenoid control module 2600, speaker module 2700, and character display subsystem 2800.

With reference to FIGS. 4 and 6, data acquisition subsystem 2200 includes a 12 bit analog to digital converter (ADC) 2210 and an analog circuit 2220. ADC 2210 is preferably a model LTC1290, available from Linear Technology Corporation, Milpitas, Calif. and is interfaced to microprocessor 2000 via a three wire serial interface and a chip select line. The serial interface includes control lines serial clock SCLK, data in DIN, and data out DOUT, respectively at pins 18, 17, and 16 of ADC 2210. These control lines are connected to lines serial clock SCK, master out slave in MOSI, and master in slave out MISO at pins 24, 23, and 22 of microprocessor 2000.

Lines SCK, MOSI and MISO of microprocessor 2000 are internally associated with the serial peripheral interface (SPI) feature of microprocessor 2000 which is programmed to run as "master" in this embodiment. The SPI allows a stream of bytes of arbitrary length to be simultaneously sent and received by microprocessor 2000. Bytes sent serially to the DIN input of ADC 2210 are interpreted as digitized data points.

Input CS/ at pin 15 of ADC 2210 is connected to line A7 at pin 27 of microprocessor 2000 and is manipulated under software control to facilitate communication to and from ADC 2210. A logic low signal on this line causes data to be simultaneously shifted in and out of lines DIN and DOUT, respectively. A logic high signal on this line cause ADC 2210 to ignore data present on line DIN and causes the DOUT line to float.

Analog module 2220 generates a voltage proportional to flow across sensor 3300 as determined by a differential strain gage pressure transducer 2222. Module 2220 includes an instrumentation amplifier 2221, pressure transducer 2222 (corresponding to element 3301 illustrated in FIG. 4), a constant current source 2223, a low pass filter circuit 2224, and a gain and offset circuit 2225.

Transducer 2222 is preferably a wheatstone bridge strain gage pressure transducer capable of producing a signal over a pressure range of plus or minus 10 inches of water. One such transducer device is model NPH-8-02.5DH available from Novasensor Inc., Fremont, Calif. Transducer 2222 is excited by constant current source 2223, an operational amplifier 2231 configured to provide approximately 1.5 ma. Input to transducer 2222 are the pressures communicated through tubes 3307 and 3308 from ports 3302 and 3303 of sensor 3300 which are converted to electrical signals by transducer 2222. The output electrical signals produced at pins 4 and 10 of transducer 2222 are provided to input pins 3 and 6 of instrumentation amplifier 2221. Input at pin 5 of transducer 2222 is a reference voltage Vcc of +5 volts fed across a resistor 2230 having a resistance of 1.5 K Ω .

Instrumentation amplifier 2221 is preferably a model LT1101 available from Linear Technology, Fremont, Calif., and is configured with a reference voltage -Vcc of -5 volt input to pin 4, and a reference voltage Vcc of +5 volts input to pin 5, respectively fed across parallel decoupling capacitors 2233 and 2234 each having a capacitance of 0.1 microfarads. Amplifier 2221 provides a gain of about 100.

The outputs at pins 1 and 8 of amplifier 2221 are fed forward to filter 2224. Filter 2224 is configured as a 28 Hz, 4 pole active low pass filter having a gain of about 4. This circuit acts as an anti-aliasing filter prior to the anticipated 60 Hz sampling rate of analog to digital conversion. Filter circuit 2224 includes two operational amplifiers 2236 and 2237 having identical circuit configurations that are connected in series as illustrated in FIG. 6. Resistors 2240 are 51.1 K Ω , resistors 2241 are 64.9 K Ω . Resistors 2242 are 102 K Ω . Capacitors 2243 are 0.22 microfarads and capacitors 2244 are 0.022 microfarads.

The filtered output signal is passed through circuit 2225 to offset adjust the signal for a final gain of about 1200. Circuit 2225 includes amplifier 2238 configured as illustrated in FIG. 6. Resistor 2250 is 100 K Ω , resistor 2251 is 330 K Ω , capacitor 2252 is 0.01 microfarads, resistor 2254 is 100 K Ω , and potentiometer 2253 has a maximum resistance of 100 K Ω . Potentiometer 2253 is preferably a conventional multiturn potentiometer that

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25

provides for nulling the offset prior to beginning any flow measurement. The function could be provided by a digitally controlled potentiometer under software program control. The four operational amplifiers of circuit 2220 are preferably contained within a single device, part No. LP324, available from National Semiconductor, Santa Clara, Calif.

The differential pressure inputs of transducer 2222 are in communication with airway 3140 through port 3302 and 3303 via tubes 3307 and 3308. Thus, in operation, air flow through sensor 3300 causes a pressure drop across resistor screen 3305 that varies with the flow. Analog module 2220 thus provides an output signal FLOW having a voltage proportional to flow and a sign, plus or minus, that indicates the direction of flow being detected.

Output FLOW of circuit 2220 is fed to pin 1 of ADC 2210 via channel 1 of the internal analog multiplexor. This input is configured under program control to function in a bipolar, singled ended mode.

Referring to FIGS. 4 and 7-9, LED annunciator modules 2300, 2400, and 2500 are similarly configured and each includes respectively one transistor switch 2301, 2401, and 2501 controlling a single light emitting diode 2302, 2402, and 2502, where each of diodes 2302, 2402 and 2502 emit light at a different color of the visible spectrum, more particularly amber, green and red respectively. Appropriate LEDs are part numbers LN48YCP (amber), LN48GCP (green) and LN48RCP (red), each available from Panasonic, Japan.

For each of modules 2300, 2400 and 2500, each switching transistor is driven, via a base current limiting resistor, by the corresponding digital output at each of pins 20, 31, and 21 of microprocessor 2000. When the transistor conducts, current flows through the LED to ground through a collector current limiting resistor. Each of the circuits are respectively configured with transistors 2301, 2401, and 2501 having base resistors 2303, 2403, and 2503 of 1.5 K Ω , LEDs 2302, 2402, and 2502 in series with collector resistors 2304, 2404, and 2504 each having 240 Ω in series with reference voltage Vcc of +5 volts, and the transistor emitters tied to ground.

Referring to FIGS. 4 and 10, microprocessor 2000 controls the operation of solenoid valve 3150 under software control through module 2600. In operation, module 2600 causes solenoid valve 3150 to deliver a pulse of aerosolized medication when the digital output line PA5 at pin 29 of microprocessor 2000, delivered to module 2600 as line SOLO, is brought high. Module 2600 includes amplifier 2610, current limiting base resistor 2621 (200 Ω), switching transistor 2620, resistor 2630 (12 K Ω) and capacitor 2631 (3300 picofarads) connected in series, and collectively in parallel with diode 2640 and in parallel with the inputs of solenoid valve 3150 as illustrated in FIG. 10. Solenoid valve 3150 is preferably model No. LFHA1200160H, available from Lee Corporation, Westbrook, Conn., and includes an integral solenoid and valve mechanism wherein the valve is operated by the solenoid. Amplifier 2610 is preferably an amplifier from device model LP324 available from National Semiconductor, Santa Clara, Calif., and is configured in a voltage follower mode. The combination of resistor 2630, capacitor 2631 and diode 2640 suppresses surges during the firing of solenoid valve 3150. Diode 2640 is preferably a conventional model No. 1N4004 diode.

26

When input signal SOLO is brought high, transistor 2620, preferably a model 2N2222 available from Motorola, Inc., Phoenix, Ariz., conducts to cause current to flow through solenoid valve 3150. This causes valve 3150 to open to release a dosage of medication from canister 3200 through flow system 3130 for delivery to and inspiration by the patient. When signal SOLO is brought low, the current stops and valve 3150 closes, terminating the dosage pulse. In accordance with the present invention, the operation of the solenoid valve 3150 is controlled by microprocessor 2000 under software control to provide for improved delivery of aerosolized drugs to the patient's lungs.

Referring to FIGS. 4 and 11, speaker module 2700 is a one transistor amplifier controlling an audio transducer 2740. A preferred transducer 2740 is model No. EAF-14RO6C, available from Panasonic, Japan. Module 2700 includes transistor 2720, preferably a model 2N2222 available from Motorola, Inc., Phoenix, Ariz., configured with a base current limiting resistor 2730 having 1.5 K Ω , a reference voltage Vcc of +5 volts fed across, in parallel, collector resistor 2730 having 300 Ω and audio transducer 2740. The transistor emitter is grounded. Input to module 2700 is signal TONE from line PA4 at pin 30 of microprocessor 2000. When transistor 2720 conducts, current flows through collector resistor 2730 and speaker 2740 through the collector of transistor 2720. The current through speaker 2740 is thus the collector current of transistor 2720 when saturated minus the current through resistor 2730. Line PA4 of microprocessor 2000 will be switched under program control so as to introduce a square wave of varying period to the input signal TONE. In this manner, an audible tone proportional to airway flow will be generated.

The audible tone is useful for cuing the patient to breathe in consistent patterns from time to time. In an alternate embodiment, a learning sequence can be programmed into microprocessor 2000 whereby a preselected signal TONE is generated to teach the patient to breath in accordance with a desired breathing pattern for optimal delivery of the particular drug to be administered. Thus, the flow detected can be compared to the preselected signal TONE such that feedback techniques, e.g., using the LED modules, can be used to train the patient to breath in a desirable manner.

In alternate embodiments, speaker 3740 could be replaced by a piezoelectric sheet or material capable of producing audible vibrations or tactile vibrations, the latter being particularly useful for deaf patients.

Referring to FIG. 4, character display subsystem 2800 allows bytes of numeric character data to be sent via the SPI of microprocessor 2000 to a multisegment LED character display 2830. A preferred display 2830 is a model No. NSM2416, available from National Semiconductor, Santa Clara, Calif. The byte representing a single character to be displayed is sent to shift register 2810 via the SPI of microprocessor 2000. This serial interface is configured in a unidirectional manner so that data can be provided by microprocessor 2000 but no data can be sent to microprocessor 2000 over line MISO. All data sent over the SPI will appear on input line DIN at pins 1 and 2 of shift register 2810 and will be clocked in. However, data will only be loaded into display 2830 when the digital output line PD5 at pin 25 is asserted by being brought low. Each byte sent to shift register 2810, preferably model no. 74HC164, available from Motorola, Inc., Phoenix, Ariz., intended for char-

acter display must contain the ASCII code of the character to be displayed in bits <0:4> and the two bit position address (00=display position 0; 11=display position 3) of the display location in which the character is to appear in bits <5:6>. The most significant bit (bit <7:7>) is ignored. The outputs of shift register 2810 and display 2830 select line are conditioned by buffers 2820, (preferably part No. 74HC244, available from National Semiconductor, Santa Clara, Calif.). This is done to allow CMOS level signals from microprocessor 2000 and shift register 2810 to drive inputs of the TTL display 2830.

In an alternate embodiment, display module 2800 may be configured under appropriate software instruction (not shown) and with additional hardware and wire connections so that the full set of ASCII coded bits can be transmitted for providing visual prompt alphanumeric information to the patient and to display various measured parameters to the patient and the medical examiner. Such a display module 2800 could be used to instruct the patient how to use the device for measuring a pulmonary function, specifically FEV1, or to obtain a desirable inspiratory flow. These instructions could include, for example, "take a breath now" indicating that the device is ready, "hold your breath longer" during an inspiratory pause period or other messages, for example, whether or not to breath harder on expiration. Thus, in addition to displaying the number of does remaining, display module 2500 can be used on the one hand to prompt the patient to breathe in accordance with selected flow patterns for measuring specific pulmonary functions, and on the other hand to prompt the patient to breathe consistently from breath to breath and thus optimize use of the device for the intended drug therapy.

Further, display module 2800 also could be used under appropriate software programming (not shown) to display the amount of medication dispensed or given effectively, which may differ from the amount dispensed and the amount of medication remaining, and provide a clinical acuity index more detailed than that provided by LED annunciator modules 2300, 2400 and 2500. Also, display module 2800 be used to instruct the patient to contact the medical examiner in the event of a determined lack of improvement in the patient's measured pulmonary functions over a predetermined period of time during the course of treatment, a determined decline in condition or a repeated inability to deliver medication in either or both of ProgBreathMode or CalBreathMode (as described below).

Similarly, display module 2800 can provide the patient alphanumeric information regarding the times and dates medication is to be administered, battery condition, and diagnostics for the condition and operation of the device, and, in conjunction with microprocessor 2000 and speaker 2740, generate a tone when the conditions require servicing the device or a battery needs to be changed.

Referring to FIGS. 12 and 13A-13E and the software appendix, a software flowchart and subroutine calling chain corresponding to the program of the software appendix are illustrated. Subroutines 100 automatically perform system initialization on Reset. Control then transfers to system main loop IdleLoop 000 which repetitively executes subroutines CheckAlarm 200, GetDataPoint 300, CheckThreshold 400, IntegrateOn 500, LoggingOn 600, ProcessBreath 700, IntegrateOff 1000,

and LoggingOff 1010, in accordance with the algorithm described below, forever.

Subroutine 200 checks the system's real time clock and compare the current time (in hours) to a stored list of recommended dosing times for the patient and the selected medication. If the current hour appears on this list, subroutine 210 causes microprocessor 2000 to provide a signal TONE to generate an audible alarm on module 2700 once for that hour. In the present embodiment the alarm serves as a recommendation to the patient that a dose is to be taken, but does not control or alter the function of the rest of the program. After the alarm clock functions have been performed, control transfers to subroutine GetDataPoint at branch point 300 which measures the instantaneous flow in airway 3140.

Referring to FIGS. 12 and 13C, flow is measured by the series of routines beginning with GetDataPoint. These routines perform data acquisition, signal processing, calibration, integration, data logging and information display functions.

Routine GetDataPoint begins by holding for a real time interrupt WaitForRTI, resulting in a 60 Hz sample rate because of initial configuration by the ConfigRTI routine executed during the Reset sequence. On a 1/60 second real time event mark, a flow data point is acquired from ADC 2210 by routine AcquireSignal.

The datapoint obtained from ADC 2210 by AcquireSignal is a 12 bit signed quantity (without sign extension). Signal processing begins by removing the lower two bits, which are assumed to be noise, by routine TrimLowBits, and proceeds with subsequent application of an 8 element moving average low pass digital filter by routine LowPassFilter.

The trimmed, low pass filtered flow data point value is then converted to its absolute value by routine AbsoluteValue and the sign bit stored for subsequent use by decision points requiring flow direction information (sign bit unity=>inhalation, sign bit zero=>exhalation).

The absolute value of the trimmed, filtered flow data point is then converted to a binary representation of flow in liters per minute by application of routine CalFlow. A rough conversion is first obtained by multiplying the uncalibrated value by two. A more accurate calibration is possible by applying correction factors to this rough calibrated value as a function of value. In the limit, one could store $2^n - 1$ correction factors for an N bit value, thereby forming a calibration array for application to each digitized data point for overcoming arbitrary nonlinearity in the mapping of the differential pressure and the flow rate. In this embodiment, the array comprises 16 correction factors which are stored in a lookup table and applied to the rough calibrated value based on the value of the high four bits. Such an approach enables airway pneumotachs with non-linear pressure/flow characteristics to be employed. The details of the calibration algorithm are explained in the software appendix code listing under the section labeled Flow Calibration Data, although the calibration constants were set to zero in that embodiment for testing purposes.

The processed flow data point is then sent as argument to the integration routines Integrate. An integration algorithm described in detail in the code listing section labeled Integration Data is then performed.

The processed flow data point is then logged and the data display (showing the value of the shot counter, i.e.,

how many dosages of medication remain in canister 3200) is updated. If this flow is above the noise threshold, program control is transferred to branch point 500 and the breath processing functions, otherwise control returns to branch 200 and CheckAlarm and the alarm check functions are again executed.

Referring to FIGS. 12 and 13B, the breath processing functions begin at point 500 which starts the real time integration of measured airway flow to yield volume. Data logging is then begun at branch point 600 by storing the date, time and mode information in the data logging array in memory module 2100. The mode information is either ProgBreathMode at branch point 720 or CalBreathMode at branch point 730 as described below.

Subroutine ProcessBreath next begins at branch point 700 by further branching based on flow direction to the exhalation (peak flow meter function) or inhalation (drug delivery) routines.

Referring to FIGS. 12 and 13D, the inhalation function begins at branch point 710 by checking for the current mode for drug delivery. If the device is in ProgBreathMode, or the device operates in the default mode (ProgBreathMode), the routine ProcessInspiration attempts to deliver drug at pre-programmed absolute flow and volume firing points. This process begins at branch point 810 where the flow and volume firing points pre-programmed in non-volatile system memory are copied into vectors FlowPoints and VolPoints (see Firing Point Data area the software appendix in code listing). This process results in the production of "scheduled flow/volume firing points." An audible tone proportional to the instantaneous measured airway flow is started at point 820. Routines 830 continuously monitor the measured flow rate and volume during the inspiration and deliver drug as each successive pre-programmed flow/volume firing point now in vectors FlowPoints and VolPoints is reached. A flow/volume firing point is defined as a point during inspiration where both the instantaneous flow rate and flow volume are greater than or equal to a preprogrammed flow rate and flow volume pair.

Routines 830 then deliver drug as each firing point is reached. Routines 840 decrement the shot counter which provides a numeric character display for the user indicating the number of doses of drug remaining, and advance pointers stored at NxtFireFlow and NxtFireVol. These pointers will then be indicating the next flow/volume firing point (if preprogrammed) stored in vectors FlowPoints and VolPoints.

Flow/volume firing information for the Programmed Breath Mode is stored in the Firing Point Data area in the software appendix code listing. The FireCount variable encodes the maximum number of possible firing points. Vectors FireFlow and FireVolume together encode flow/volume firing point pairs where FireFlow[i] and FireVolume[i] refer to firing point i. Flow rate is expressed in liters per minute, flow volume in liters. Preferably, as each firing point is reached, a uniform pulse is generated. In an alternate embodiment, variable size pulses may be generated in accordance with a selected schedule relating the time of delivery of the successive firing points to the desired location of deposition of the aerosol particles.

If the system is currently in CalBreathMode, i.e., calibration breath mode, control is transferred at branch point 710 to the routines ComputeCalPoints at branch point 800. These latter routines load the FlowPoints and VolPoints flow/volume firing point data arrays. Instead

of copying pre-programmed flow/volume firing point data into the FlowPoints and VolPoints arrays as was done by routine ComputeProgPoints, routines at branch point 810, routines ComputeCalPoints at point 800 calculate flow/volume firing points based on the flow/volume maxima achieved during the preceding breath. This process results in the production of "scheduled flow/volume firing points."

Vectors PctFireFlow and PctFireVol contain the pre-programmed percent of maxima information used by routines ComputeCalPoints to make the flow/volume firing point calculations. These percent factors are encoded as the number of right shift operations needed to generate the desired percentage from a binary representation of the original value. Thus, unity represents 50%, two represents 25%, three represents 12.5% and so on.

Routines ComputeCalPoints apply percentage information contained in vectors PctFireFlow and PctMaxFlow to flow and volume maxima, respectively, measured during the last breath. A plurality of absolute flow/volume firing points (the exact number of firing points determined, as in ProgBreathMode, by the pre-programmed variable FireCount) are constructed, and placed in the FlowPoints and VolPoints vectors.

Control is then transferred to routines 820 and 830, and are again used, as they were in ProgBreathMode, to start an audible tone proportional to measured airway flow (routine EnableTone at branch point 820) and to deliver drug at the now appropriate flow/volume firing points (routines 830). The flow/volume firing points now resident in vectors FlowPoints and VolPoints are again consulted by routines 830 and used to trigger solenoid 3150 upon satisfaction of these thresholds.

It is the plurality of flow/volume firing point data loaded into the FlowPoints and VolPoints vectors by routines 800 and 810 respectively that distinguishes the behavior of the system during CalBreathMode and ProgBreathMode. In particular, during ProgBreathMode an attempt is made to deliver drug at invariant, pre-programmed firing points. During CalBreathMode, an attempt is made to deliver drug at flow/volume firing points determined through the application of pre-programmed percentage constants to the flow and volume maxima determined during the previous breath.

After all single inhalation scheduled drug deliveries have been made, or when measured flow changes direction, the audible tone proportional to flow is disabled by routine 850 and the appropriate mode for the next breath is determined at branch point 700. If some drug was delivered, it is assumed that the patient was making an acceptable inspiratory effort (even though all scheduled drug deliveries may not have taken place). In the case that some drug was delivered, the next mode will be ProgBreathMode, selected by routine ProgMode at branch point 720. On the other hand, if no drug was delivered, the assumption is made that the patient made an inadequate inspiratory effort, and was unable to meet any of the flow/volume firing point criteria for the previous breath. In this case, CalBreathMode is selected for the next breath by routine CalMode at branch point 730.

By entering CalBreathMode, the system is accommodating to individual patient characteristics when the patient has demonstrated an inability to generate sufficient inspiratory flow and volume to meet even one scheduled flow/volume firing point. By calculating new firing points as a fraction of flow/volume param-

ters actually achieved during the previous breath, the chance of achieving a drug delivery during the subsequent breath becomes more likely. In other words, if none of the more desirable (i.e., relatively late in the cycle) scheduled flow/volume firing points can be met by a patient's inspiratory effort, then new scheduled flow/volume firing points occurring earlier in the inspiratory cycle, i.e., at relatively lower flow rates and flow volumes, are more desirable than no drug delivery at all.

In accordance with the present invention, if no drug is delivered during an inspiration in the CalBreath-Mode, CalBreathMode will again be entered, and new scheduled flow/volume points corresponding to lower flow rates and volumes will be calculated based on the new flow/volume maxima achieved during the most recent previous breath. This strategy virtually ensures that some drug will be eventually delivered, even if the patient's inspiratory effort is deteriorating from breath to breath.

Referring to FIGS. 12, 13B, and 13D, after selection of the next breath mode by routines ProgMode at point 720 or CalMode at point 730, the integration process is stopped by routine IntegrateOff at point 1000 and the data logging stopped by routine LoggingOff at point 1010. During each breath, a log of all measured flow data is kept in an array into which is also stored the time and date, mode and (flow) points in the array where drug was delivered. The format of this array can be found in the software appendix code listing in the section labeled Data Logging Area.

This completes the description of the behavior of the software branching routines during an inhalation.

Referring to FIGS. 12, 13B, and 13D, if an exhalation is detected at decision branching point 700, control is transferred to exhalation handling routines ProcExpiration at branching point 900. Routine EnableTone at point 910 activates an audible tone proportional to measured airway flow. Flow is continuously measured and data points are logged until flow direction reverses. Routines 920 detect peak flow by noting the flow prior to the point of flow reversal. This peak flow point is mapped into a three level clinical acuity index by routines DisplayAcuity at point 940 through the use of pre-programmed constants stored at AcuityGreen, AcuityAmber and AcuityRed. The appropriate declarations can be found in the software appendix code listing in the section labeled Pulmonary Function Data.

If the measured peak flow is greater than or equal to the value stored at AcuityGreen, a green light emitting diode is illuminated by routines 940 indicating that the patient's condition is nominal. If the measured peak flow is greater than or equal to the value stored at AcuityAmber, and less than the value stored at AcuityGreen, an amber light emitting diode is illuminated by routines 940 indicating that the patient's condition is marginal. If the measured peak flow is greater than or equal to the value stored at AcuityRed, and less than the value stored at AcuityAmber, a red light emitting diode is illuminated by routines 940 indicating that the patient's condition is unacceptable.

Subsequent to display of the acuity index, the integration is stopped by routine IntegrateOff at point 1000. Note that volume information is not used during the processing of an exhalation by this embodiment. However, in an alternate embodiment, such volume data could be used to calculate valuable pulmonary function indices such as the FEV1 (volume exhaled in one sec-

ond) and vital capacity (VC). The FEV1 could be used to provide more clinical acuity information to the patient than the three level index based on peak expiratory flow now displayed. Further note that, although the volume information is not being used to calculate the FEV1 in this embodiment, the FEV1 could be calculated later through analysis of the logged flow points of data.

Control then continues to routine LoggingOff at point 1010 which stops data logging, as was done during inhalation mode described earlier.

The preferred embodiment makes extensive use of internally programmed constants which influence the system behavior. These constants are readily changed in the current embodiment through the use of a microprocessor emulator system which allows an MS-DOS computer to be used to arbitrarily modify a plurality of non-volatile system memory locations containing either program or data.

It is intended that the software programs be flexible in design so that the system can be configured for use with a particular patient by selecting certain processing sub-routines, calibration coefficients, and operating parameters from a library of such information, or from an external source, for use by the main program to accommodate patient specific or drug specific requirements in different applications to treat predetermined medical conditions. Thus, the software controlling the device can be configured or customized for a specific use by a specific patient. Accordingly, when the device is used for a different patient or medication or both, the software can be reconfigured for such use.

In another alternate embodiment of the present invention, the software is programmed to measure pulmonary function periodically, preferably prior to each administration of a dosage, and look for changes in the detected flow patterns and measured pulmonary functions of the patient during the course of treatment. Those detected changes are then used to modify the treatment parameters in accordance with the improved or degenerated condition of the patient. For example, the dosage per administration and the frequency of administration could be adjusted as indicated by detected changes in the patient's condition. Similarly the dosage could be adjusted from administration to administration by measuring the time between administration to determine a maximum allowed dosage based on accepted medical practices.

In another alternate embodiment of the present invention, each canister 3200 is provided with a code that identifies the contents of the canister, and system electronics 3400 includes means (not shown) for reading a code associated with canister 3200. In one such embodiment, the code is entered externally and in another such embodiment the code is provided automatically when canister 3200 is inserted into base 3100. The code may be read each time canister 3200 is inserted into base 3100 and used by microprocessor 2000 to customize the software programming for delivery of the particular medication. In one embodiment, the code is in the form of product labeling, e.g., a universal bar code, and a code sensor for reading a printed universal bar code (not shown) comprises a photodetector array and a light emitting diode to provide illumination for the photodetector array to read the bar code. Preferably, the bar code is of the circular form so that it can be read regardless of the orientation of canister 3200 in base 3100. In another embodiment, the code may be a digital word

**SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIRECCION DE NUEVAS CREACIONES**

2020
Bogotá, D.C.,

Abogado
Dr. RICARDO METKE MENDEZ.

ASUNTO	Radicación	05 - 88375
	Trámite	011
	Evento	379
	Actuación	430
	Oficio	009058
	Folios	19

Patente de Invención	☒	Patente de Modelo de Utilidad	☐
Vía Nacional	☐		
Vía PCT (fase nacional)	☒	Cap. I	☒
		Cap. II	☐
No. Sol. Internacional	<u>PCT/US2004/006511</u>		
Fecha de Presentación Internal.	<u>2004/03/04</u>		

Como resultado del examen de fondo, realizado con fundamento en el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se comunica:

1. Documentos estudiados

<u>Descripción:</u>	Folios: 58 a 101	Como se radico inicialmente.
<u>Reivindicaciones:</u>	Folios: 102 a 112	Como se radico inicialmente.
<u>Dibujos:</u>	Folios: 113 a 130	Como se radico inicialmente.
<u>Prioridad:</u>	Folios: 1	(GB) 2003-0304905.3 (2003/03/04). (US) 2003-60/452.260 (2003/03/05). (US) 2004-0401649.9 (2004/01/26).

2. Objeto de la invención

Título de la invención: **"DISPOSITIVO DISPENSADOR DE MEDICAMENTO CON UNA PANTALLA INDICADORA DEL ESTADO DEL RESERVORIO DE MEDICAMENTO INTERNO". (Folio 1).**

Problema Técnico Planteado:

- Evitar dispensar cantidades o dosis inexactas de medicamentos en un dispensador de medicamentos de un recipiente o reservorio, e igualmente evitar la incertidumbre de la cantidad y el nivel de medicamento que se encuentra almacenado en el recipiente al paciente o usuario que tiene a su disposición.

Solución:

La solución a los problemas técnicos planteados es proporcionar un dispositivo dispensador de medicamento con una pantalla indicadora del estado del reservorio de medicamento interno, la cual consta de un dispositivo convencional y un sistema de ensamble indicador electrónico para ver la cantidad y suministrar el dispensado exacto de la dosis de medicamento contenida en un recipiente para que el usuario o paciente la emplee en su tratamiento médico.

IPC: **A61M11/00, A61M11/02, A61M15/00, A62B7/00, B65D83/06.**

3. Análisis de la solicitud de Patente

Reivindicaciones (*artículo 30 D 486, Art 22 PCT*).

Claridad:

- En la reivindicación independiente No.1, se evidencia que es muy extensa, no es clara y concisa debido a que no se muestra claramente y concretamente que elementos o características técnicas esenciales se desean proteger y la hacen diferente frente al estado de la técnica.

En la reivindicación No.1, se evidencia que ilustra los siguientes elementos o características *"medios de identificación para presentar información indicativa de una identidad de dicho recipiente", "un detector", "medios para detectar dichos movimientos de suministro de medicamento"*, se evidencia que estas características o elementos son circuitos electrónicos o medios electrónicos, como sensores, circuitos electrónicos y pantallas adaptados e insertados en el dispositivo dispensador con el fin de indicar y suministrar la cantidad exacta de medicamento que queda en el recipiente al paciente, en donde todos estos elementos o características son conocidos dentro del estado de la técnica que simplemente se adaptan a este dispositivo, en donde se evidencia que las pantallas o displays simplemente presentan una información al usuario y la parte electrónica es un soporte lógico para llegar a procesar un movimiento mecánico y transformarlo en una señal lógica eléctrica o electrónica donde se procesa dicha información para mostrarla en definitiva al usuario, estos elementos o características tal y como están reivindicados no serán considerados como una invención.

Se le sugiere al solicitante presentar una nueva reivindicación independiente No.1, que contenga en el preámbulo los elementos conocidos en el estado de la técnica y en la parte caracterizadora presentar los elementos y/o características novedosas de manera clara, concreta y que la hacen diferente del estado de la técnica.

Se le recuerda al solicitante que en la reivindicación independiente, la parte caracterizadora, que suele seguir al preámbulo precedida por la frase **"caracterizado por"**, recoge las características técnicas que van hacer protegidas y que constituyen la novedad frente al objeto conocido del estado de la técnica.

Se le recuerda al solicitante que según la decisión 486 de la comunidad andina dice que en el **"Artículo 15.- No se consideraran invenciones:**

- e) los programas de ordenadores o el soporte lógico, como tales; y,
 - f) las formas de presentar información".
- En la reivindicación independiente y en el siguiente grupo de reivindicaciones dependientes, se evidencia que ilustran elementos, características, componentes o términos, que no son claros, no se definen de manera específica y concreta a que elementos se están refiriendo y/o cuales elementos pertenecen, debido que esta invención se compone de varias piezas establecidas e ilustradas en la invención, así:
 - No.1. "Carcasa", "Región vacía central",
 - No.1. "Recipiente para un medicamento reservorio Interno".
 - No.1. "Reservorio interno", "Reservorio".
 - No.1. "Puerto de suministro".
 - No.1. "Medios para sostener dicho recipiente para medicamento".
 - No.1. "Medios de identificación unidos a dicho recipiente".
 - No.1. "Detector", "Montaje con indicador de estado de recipiente".
 - No.1. "Medios para detectar movimientos de suministros".
 - No.1. "Señal indicativa del estado de dicho recipiente".
 - No.2. "Recipiente por uno de al menos dos estados".
 - No.3. "X1 es un primer número predeterminado".
 - No.3. "Segundo estado indicativo de dicho reservorio que contiene menos de X1 dosis".
 - No.4. "Indicador de estado de recipiente", "Pantalla grafica".
 - No.4. "Pantalla grafica".
 - No.4. "Campo de medicamento", "Campo exterior de campo".
 - No.4. "Región interior vacía", "Segundo estado".
 - No.5. "Campo exterior en forma de recipiente".
 - No.6. "Campo exterior tiene una forma rectangular".
 - No.7. "ampo exterior tiene forma triangular".
 - No.8. "Menos tres estados".
 - No.9. "X1 es un primer estado seguro siendo un estado seguro".
 - No.9. "X1 es un primer número predeterminado".
 - No.9. "X2 es un segundo numero predeterminado".
 - No.9. "X2 dosis de medicamento".
 - No.9. "X2, dicho segundo estado es un estado de PRECAUCION".
 - No.14. "Recipiente de aerosol".
 - No.16. "Medios de identificación es un dispositivo RFID".
 - No.17. "Detector", "Medios de identificación", "Resorte cargado".
 - No.17 y No.18. "Contactos fijos", "Carcasas", "Recipiente", "Contacto de un resorte".
 - No.18 y 20. "Indicador de estado",
 - No.19. "Pantalla que indica dicha señal VALIDA o INVALIDA generada por dicho detector".
 - No.20. "Pantalla para indicar dicha señal generada por dicho indicador de estado de recipiente".
 - No.21. "Pantalla de cristal liquido (LCD)".
 - No.22. "Pantalla comprende un dispositivo de diodo emisor de (LED)".
 - No.23 y 24. "Pantalla comprende un interruptor", "carcasa".
 - No.24. "Pantalla comprende un interruptor con un botón de control accesible desde la parte externa".

- No.26 y 27. "Manguito unido a dicho recipiente", "Medios de identificación están unidos a dicho manguito".
- No.27. "Puerto de suministro".
- No.28. "Manguito", "Porción intermedia".
- No.29. "Manguito que comprende una costilla longitudinal".
- No.29. "Carcasa", "Costilla longitudinal", "Ranura".
- No.30. "Indicador de estado", "Dispositivo de memoria".
- No.31. "Medios para detectar dichos movimientos de suministros de medicamento".
- No.31 y 32. "Montaje de interruptor", "contador".
- No.32. "Pista eléctricamente conductora sustancialmente en forma de U".
- No.32. "Dos contactos unidos al otro de dichos recipientes".
- No.33. "Generador de campo inductivo", "Carcasa".
- No.33. "Detector inductivo"

Se le sugiere al solicitante que coloque de manera específica y concreta a que elementos, características, componentes o términos, se está refiriendo, colocando al frente de la característica o del elemento, el número de referencia guardando correspondencia con el capítulo descriptivo, las gráficas o dibujos y dicho capítulo reivindicatorio, con el objetivo de comprender mejor la invención al momento de hacer el análisis y distinguir los elementos de dicha invención.

- En los siguientes grupos de reivindicaciones dependientes, se evidencia que tal como están reivindicadas, exponen el mismo contenido o son similares, así:
 - No.4, No.9 y No.10.
 - No.5 y No.11.
 - No.6 y No.12.
 - No.7 y No.13.

Se le sugiere al solicitante que unifique aquellas reivindicaciones dependientes que exponen el mismo o similar contenido.

- En la reivindicación dependiente No.3 y 9, se evidencia que hay términos que no son claros, no son precisos debido a que exponen términos como *"X1 es un primer número predeterminado y dicho primer estado es un estado seguro"* y *"el segundo estado indicativo de dicho reservorio que contiene menos de X1 dosis, dicho segundo estado es un estado de prevención"*, *"X1 es un primer estado seguro siendo un estado seguro"*, *"X1 es un primer número predeterminado"*, *"X2 dosis de medicamento"*, *"X2, dicho segundo estado es un estado de PRECAUCION"*.

Se le sugiere la solicitante suprimir o redactar nuevamente estas reivindicaciones colocando de manera clara, concreta y precisa a que términos o rangos se está refiriendo.

- En las reivindicaciones independientes No.4, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, y 33, se evidencia que ilustra los siguientes elementos o características *"dispositivo de pantalla gráfica"*, *"Detector"*, *"Medios de identificación"*, *"Resorte cargado"*, *"Indicador de estado"*, *"Pantalla que indica dicha señal VALIDA o INVALIDA generada"*.

indicador de estado de recipiente", "Pantalla de cristal liquido (LCD)", "Pantalla comprende un dispositivo de diodo emisor de (LED)", "Pantalla comprende un interruptor", "Pantalla comprende un interruptor con un botón de control accesible desde la parte externa", "Manguito unido a dicho recipiente", "Medios de identificación están unidos a dicho manguito", "Indicador de estado", "Dispositivo de memoria", "Medios para detectar dichos movimientos de suministros de medicamento", "Pantalla grafica y pantalla numérica", "Montaje de interruptor", "contador", "Pista eléctricamente conductora sustancialmente en forma de U", "Dos contactos unidos al otro de dichos recipientes", "Generador de campo inductivo", "Carcasa", "Detector inductivo", se evidencia que estas características o elementos son medios o elementos electrónicos, como sensores, circuitos lógicos electrónicos, procesadores lógicos y pantallas adaptados e insertados en el dispositivo dispensador con el fin de indicar y suministrar la cantidad exacta de medicamento que queda en el recipiente al paciente, en donde todos estos elementos o características son conocidos dentro del estado de la técnica que simplemente se adaptan a este dispositivo, en donde se evidencia que las pantallas o displays simplemente presentan una información al usuario y la parte electrónica es un soporte lógico para llegar a procesar un movimiento mecánico y transformarlo en una señal lógica eléctrica o electrónica donde se procesa dicha información para mostrarla en definitiva al usuario, estos elementos o características tal y como están reivindicados no serán considerados como una invención.

Se le sugiere al solicitante que tenga en cuenta que la presentación de información y el soporte lógico no son patentables, además se le sugiere al solicitante que redacte nuevamente estas reivindicaciones teniendo en cuenta claramente y concretamente que elementos o características técnicas particulares esenciales se desean proteger y la hacen diferente frente al estado de la técnica que componen el dispositivo dispensador de medicamento.

- En la reivindicación dependiente No.15, se evidencia que es muy extensa, no es clara y concisa, debido a que lo que se quiere reivindicar son todos los medicamentos que contienen y que se suministran y que se emplean dentro del recipiente del dispositivo dispensador por medio del montaje de dicho dispensador, además estos medicamentos no hacen parte de las características técnicas particulares que componen el dispositivo dispensador de medicamentos.

Se le sugiere al solicitante que suprima o elimine esta reivindicación.

- En las reivindicaciones dependientes No.31, 32 y 33, se evidencia que lo que se quiere proteger y reivindicar son los siguientes elementos o características *"montaje del interruptor", "una pista eléctrica, los contactos y el contador" y un "generador de campo inductivo unido o detector inductivo",* mediante un montaje de un inhalador de medicamento.

Se le sugiere al solicitante que suprima o elimine estas reivindicaciones.

- En las reivindicaciones independientes No.10 y No.15 junto con sus dependientes, se evidencia que exponen un *"método para readaptar una cerradura a llave nueva",* estas reivindicaciones, no se evidencian que ilustren un método, entendiéndose que un método o procedimiento es un

etapas de fabricación y/o manufactura para llegar a un “cilindro de cerradura adaptable a nueva llave”, en estas reivindicaciones No.10 y 15 hacen referencia a las características técnicas de funcionamiento de la cerradura cuando se requiera al momento de hacer el procedimiento de readaptación de la llave, por lo tanto no exponen un método.

Se le sugiere al solicitante que suprima o elimine estas reivindicaciones.

4. Determinación del Estado de la Técnica

Teniendo en cuenta la fecha de presentación nacional, con fecha del 02 de Septiembre del 2005, se encontraron los siguientes documentos relevantes:

Nº	Documento	Título	Fecha de Publicación
D1	US5404871	DELIVERY OF AEROSOL MEDICATIONS FOR INSPIRATION	11/04/1995

1. Respecto al estado de la técnica:

El documento **D1 US5404871** ilustra un aparato y método para entregar una cantidad determinada de medicina aerosolizada a un paciente por medio de una aspiración mecánica realizada por este, obteniendo una dosis apropiada en la cantidad del medicamento que el paciente debe consumir dependiendo su tratamiento médico. El medicamento aerosolizado podría ser administrado con uno o más pulsos eléctricos, teniendo en forma un pulso amplio, en su forma y frecuencia que maximizaría la porción o dosis del medicamento aerosolizado, siendo administrado óptimamente. (Ver “Abstract, Columnas 1 a 16 y las “figuras No.1 a No.13B”).

5. Análisis de Patentabilidad (Art 14 D486):

Novedad (Art 16 D486)

1. Respecto a la solicitud en estudio:

La reivindicación No.1 dice: “Un montaje de inhalador de medicamento que comprende:

- A. Una carcasa que define una región vacía central dispuesta a lo largo del eje central;
- B. Un recipiente para medicamento que tiene un reservorio interno que contiene medicamento, y que se extiende a lo largo de un eje de recipiente y que tiene en un extremo de este, un puerto de suministro que se extiende a lo largo de dicho eje de recipiente, dicho puerto esta acoplado a dicho reservorio;
- C. Medios para sostener dicho recipiente para medicamento dentro de dicha región central vacía con dicho eje de recipiente sustancialmente coaxial con dicho eje central, por medio del cual el movimiento inducido por el usuario en una cantidad predeterminada de dicho recipiente con relación a dicha carcasa en una primera dirección a lo largo de dicho eje origina que el medicamento sea suministrado desde dicho puerto de

- D. Medios de identificación unidos a dicho recipiente para presentar información indicativa de una identidad de dicho recipiente, dicha identidad está asociada con dicha carcasa;
- E. Un detector unido a dicha carcasa y adaptado para detectar dicha información presentada cuando dicho recipiente está dispuesto en dicha región central vacía de dicha carcasa, y para generar una señal VALIDO cuando dicha información presentada detectada corresponde a dicha información de identidad asociada con dicha carcasa, y de otra forma una señal de INVALIDO; y
- F. Un montaje con indicador de estado de recipiente unido a dicha carcasa y dicho recipiente y que incluye medios para detectar dichos movimientos de suministro de medicamento de dicho recipiente con relación a dicha carcasa, y para generar una señal indicativa del estado de dicho recipiente". (Ver folios 102, 103).

Para efectos del examen, se toma en cuenta como características técnicas esenciales las que se encuentran subrayadas por el examinador.

2. Análisis de las diferencias con respecto al estado de la técnica:

En la tabla No.1, se ilustran en las casillas de comparación, la explicación de Afirmativa si las reivindicaciones están comprendidas dentro del estado de la técnica (documento D1), en caso contrario se enunciaría como No es Afirmativa.

Tabla No.1.

ESTUDIO DE NOVEDAD	
Características esenciales de la Solicitud en estudio	Documento D1
A. Una carcasa que define una región vacía central dispuesta a lo largo del eje central;	Afirmativa (Ver "Abstract" Columna 19 (lin 1 a 67), Columna 20 (lin 1 a 67), Columna 21 (lin 1 a 67), Columna 22 (lin 1 a 67), Columna 23 (lin 1 a 67), columna 24 (lin 1 a 67), Columna 25 a 30 (lin 1 a 67), figuras 1 a 13F).
B. Un recipiente para medicamento que tiene un reservorio interno que contiene medicamento....., un puerto de suministro que se extiende a lo largo de dicho eje de recipiente....., dicho puerto está acoplado a dicho reservorio;	Afirmativa (Ver "Abstract" Columna 19 (lin 1 a 67), Columna 20 (lin 1 a 67), Columna 21 (lin 1 a 67), Columna 22 (lin 1 a 67), Columna 23 (lin 1 a 67), columna 24 (lin 1 a 67), Columna 25 a 30 (lin 1 a 67), figuras 1 a 13F).
C. Medios para sostener dicho recipiente para medicamento dentro de dicha región central vacía con dicho eje de recipiente sustancialmente coaxial con dicho eje central.....	Afirmativa (Ver "Abstract" Columna 19 (lin 1 a 67), Columna 20 (lin 1 a 67), Columna 21 (lin 1 a 67), Columna 22 (lin 1 a 67), Columna 23 (lin 1 a 67), columna 24 (lin 1 a 67), Columna 25 a 30 (lin 1 a 67), figuras 1 a 13F).
D. Medios de identificación unidos a dicho recipiente para presentar información indicativa de una identidad de dicho recipiente.....	Afirmativa (Ver "Abstract" Columna 19 (lin 1 a 67), Columna 20 (lin 1 a 67), Columna 21 (lin 1 a 67), Columna 22 (lin 1 a 67), Columna 23 (lin 1 a 67), columna 24 (lin 1 a 67), Columna 25 a 30 (lin 1 a 67), figuras 1 a 13F).
E. Un detector unido a dicha carcasa y adaptado para detectar dicha información presentada cuando dicho recipiente está dispuesto en dicha región central vacía de dicha carcasa y para generar una señal VALIDO cuando dicha información presentada detectada corresponde a dicha información de identidad asociada con dicha carcasa, y de otra forma una señal de INVALIDO; y	Afirmativa (Ver "Abstract" Columna 19 (lin 1 a 67), Columna 20 (lin 1 a 67), Columna 21 (lin 1 a 67), Columna 22 (lin 1 a 67), Columna 23 (lin 1 a 67), columna 24 (lin 1 a 67), Columna 25 a 30 (lin 1 a 67), figuras 1 a 13F).
	Afirmativa (Ver "Abstract"

3. Realizada la comparación y el análisis del documento D1, mediante la tabla No.1 con respecto a la solicitud en estudio donde se presenta la reivindicación No.1, se evidencia que D1 contiene todas las características esenciales de la reivindicación No.1. Por lo que se concluiría que la reivindicación No.1 de la solicitud en estudio no es nueva y no cumpliría con lo estipulado en el artículo 16 de la decisión 486.

Conclusión:

Los requisitos de patentabilidad de la presente solicitud se encuentran afectados así:

N°	Documento N°	Reivindicaciones Afectadas	Requisito que Afecta
D1	US5404871	1 a 33	Novedad

Se evidencia que las características o elementos que se quieren reivindicar como medios o elementos electrónicos, como sensores, circuitos lógicos electrónicos, procesadores lógicos y pantallas adaptados e insertados en el dispositivo dispensador con el fin de indicar y suministrar la cantidad exacta de medicamento que queda en el recipiente para el paciente, en donde todos estos elementos o características son conocidos dentro del estado de la técnica que simplemente se adaptan a este dispositivo, en donde se evidencia que las pantallas o displays simplemente presentan una información al usuario y la parte electrónica es un soporte lógico para llegar a procesar un movimiento mecánico y transformarlo en una señal lógica eléctrica o electrónica donde se procesa dicha información para mostrarla en definitiva al usuario, estos elementos o características tal y como están reivindicados no serán considerados como una invención.

Se le recuerda al solicitante que según la decisión 486 de la comunidad andina dice que en el "Artículo 15.- No se consideraran invenciones:

- e) los programas de ordenadores o el soporte lógico, como tales; y,
- f) las formas de presentar información".

173
177

En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de sesenta días contados a partir de la fecha de notificación de la presente comunicación. En caso de no dar respuesta al presente requerimiento, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2 literal e), del capítulo quinto del título primero de la circular única, No. 10 del 2001.


ALIX CESPÉDES DE VERGEL
Directora de Nuevas Creaciones (C)

06 AGO 2016

El anterior requerimiento fue notificado por fijación en lista, de fecha

CONCEPTO TECNICO Numero: 1560	EXAMINADOR TECNICO Código No. 202072
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