OPIC
OFFICE DE LA PROPRIÉTÉ INTELLECTUELLE DU CANADA

CIPO
CANADIAN INTELLECTUAL PROPERTY OFFICE

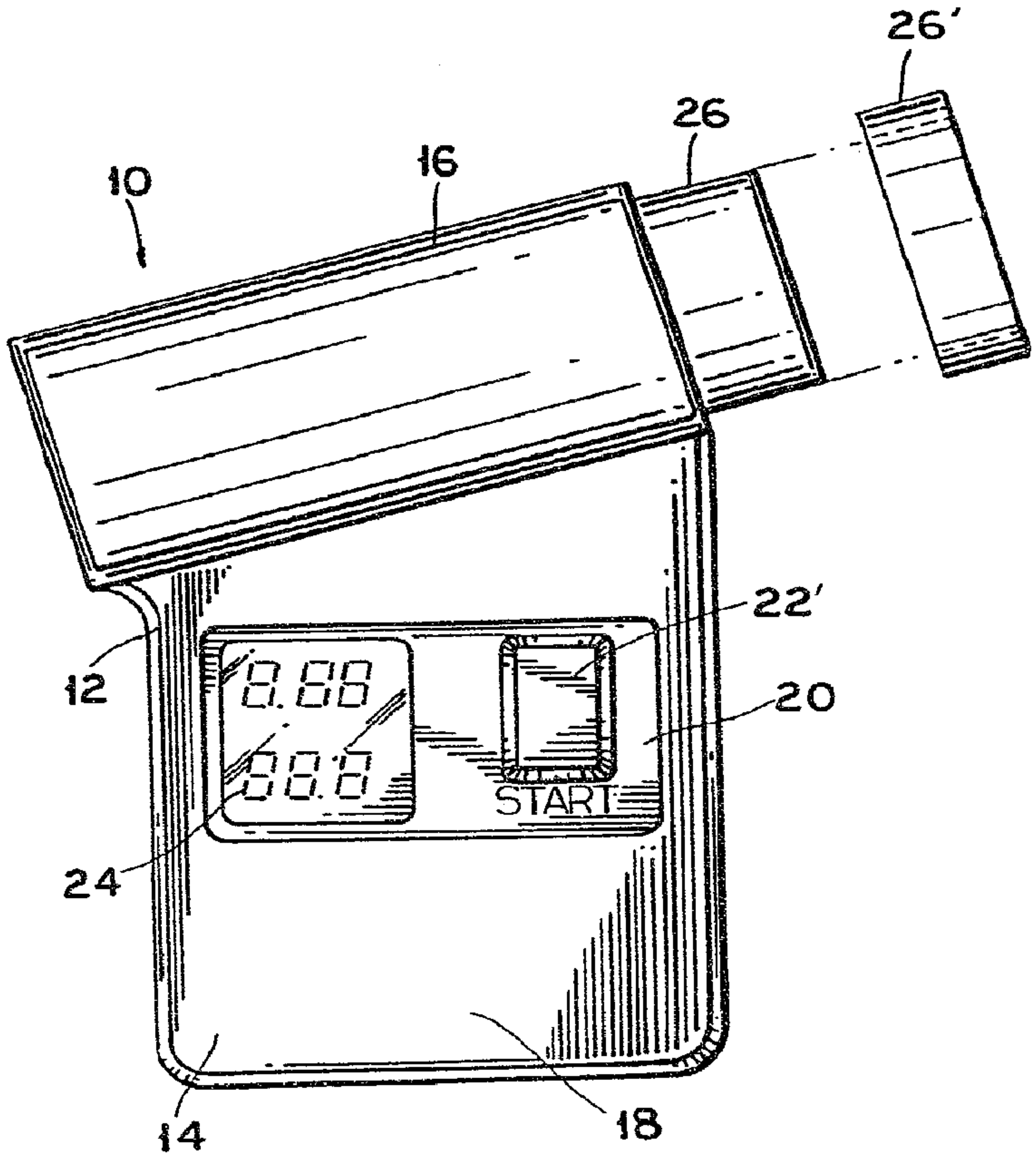
(12) (19) (CA) **Brevet-Patent**

(11) (21) (C) **2,032,796**
(22) 1990/12/20
(43) 1991/07/05
(45) 2000/12/05

(72) Waterson, Charles K., US
(72) Ebeling, Frederick A., US
(73) GLAXO WELLCOME AUSTRALIA LIMITED, AU

(51) Int.Cl.^{5} G01F 1/34
(30) 1990/01/04 (461,089) US

(54) **SPIROMETRE PERSONNEL**
(54) **PERSONAL SPIROMETER**



(57) A self-contained portable spirometer includes a housing and an air tube with an orifice. Within the housing there is a transducer and microprocessor-based circuitry for generating standard exhaled air measurements such as FEV_1 and PFER. These measurements are displayed on a screen disposed on the housing.

2032796

ABSTRACT OF THE DISCLOSURE

A self-contained portable spirometer includes a housing and an air tube with an orifice. Within the housing there is a transducer and microprocessor-based circuitry for generating standard exhaled air measurements such as FEV_1 and PFER. These measurements are displayed on a screen disposed on the housing.

3114-10

A PERSONAL SPIROMETER

BACKGROUND OF THE INVENTION

a. Field of Invention

This invention pertains to an apparatus for automatic measure of the volume and flow rate of air exhaled by a person, and more particularly, to a personal spirometer small enough so that it can be carried unobtrusively in a pocket so that person can use it easily with maximum convenience and minimum embarrassment.

b. Description of the Prior Art

Spirometers are devices used to measure the volume and flow rate of air exhaled by a person. These measurements are important for general physiological studies and for diagnostic analysis of particular patients. For example, the effects of various medicines used to treat patients with pulmonary or asthmatic problems can be best analyzed by monitoring the volume and flow rate of air exhaled at regular intervals before and after the administration of medication.

In general, spirometers make their measurement by one of two means. One type collects the exhaled volume from the subject into a bellows or other container, the displacement of which corresponds to the volume of exhaled air. These devices are by their nature large to allow sufficient air collection volume and hence are not easily made portable. A second type measures the rate of air flow through a flow measurement device. Exhaled volume is derived by integration of the air flow rate over some period of time.

Until the present invention, spirometers were rather bulky and expensive devices found mostly in clinics and laboratories. Their operation required a trained technician. Furthermore, most such devices were complicated so that they could not be made small enough to be carried in a pocket. For example, there are several devices available in the market known as pneumotachs, such as the Fleisch Pneumotach. These devices depend on a laminar air flow past a resistance element. Such devices need additional means for insuring that the flow remains laminar even at high air velocities. Therefore, these type of devices are inherently complex and relatively large. Furthermore the resistance element frequently includes a screen disposed directly in the air path. This screen intercepts impurities which clog the screen and change the response of the device and in addition are unsanitary. The pneumotach also includes pressure measurement ports which frequently become occluded from moisture or impurities, thus adversely altering the accuracy of measurement.

OBJECTIVES AND SUMMARY OF THE INVENTION

An objective of the present invention is to provide an apparatus which may be used for an accurate and instantaneous measurement of exhaled air.

A further objective is to provide a self-contained apparatus which can be made small enough to fit in a person's pocket.

Another objective is to provide an apparatus which is simple enough to be used by the subject and is reliable without special care from the user.

Yet another objective is to provide an apparatus which can be adapted for data recording.

Other objectives and advantages of the invention shall become apparent from the following description of the invention.

Accordingly, the present invention relates to a portable spirometer comprising a housing, an air tube coupled to the housing and including a substantially linear air passage with a reduced diameter orifice for generating a turbulence in the air passage, and pressure sensing means for sensing a differential pressure across the orifice when a person exhales through the air tube. Filter means are disposed at an interface between the tube and the pressure sensing means for protecting the pressure sensing means. The filter means is made of a material permeable to gases and impermeable to liquids. Electronic circuitry means is disposed in the housing and coupled to the pressure sensing means for generating electric input signals corresponding to the differential pressure. The electronic circuitry means includes calculating means for calculating performance signals from the electric input signals. Display means are also provided for displaying the performance signals.

Preferably, the spirometer displays two parameters known as FEV_1 (the volume of air exhaled in one second in liters) and PEFR (peak expiratory flow rate in liters per second). Optionally the results of several measurements may be recorded in a memory for later down-loading to a data processing system.

An adaptive start algorithm is used to detect a true test, using a statistical approach rather than a preset threshold level. More particularly, the device calculates the average and the variance of a window formed of four consecutive samples and flow rate and volume calculations are started only if a progressive increase in the measurements is detected. This approach is found to provide good sensitivity and, at the same time, it is relatively immune to noise.

Furthermore, the spirometer takes advantage of the non-linear characteristics of the air tube to increase sensitivity without expensive high resolution A/D converters. Separate look-up tables for high and low flow rates are used to convert pressure differential samples into actual flow rates.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a side view of a personal spirometer constructed in accordance with the invention;

Figure 2 shows a front view of the spirometer of Figure 1;

Figure 3 shows a cross-sectional view of the air tube of Figures 1 and 3;

Figure 4 shows an end view of the air tube of Figure 3;

Figure 5 shows somewhat schematic block diagram for the elements of the spirometer constructed in accordance with this invention;

Figures 6A and 6B show an elementary wiring diagram of a preferred embodiment of the invention; and

Figures 7A, 7B and 7C show flow charts for the operation of the microprocessor for the spirometer.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to the drawings, a personal spirometer 10 constructed in accordance with this invention includes a housing 12 with a generally square section 14 and an air tube 16 disposed on one side of the section 14. The spirometer is sized and shaped so that it can fit in a pocket. Furthermore, the spirometer is shaped and sized so that it can be held comfortably in one hand while air is exhaled through it as described more fully below. The section 14 has a flat surface 18. A control panel 20 is imbedded in surface 18 and it includes a start button 22' and an LCD display screen 24. Air tube 16 has an annular mouth piece 26 at one end sized to fit in a person's mouth. A cylindrical hole 28 passes through the air tube 16. Hole 28 has a substantially constant diameter except at an annular wall 30. This annular wall 30 forms a sharp-edged orifice within hole 28. Two small openings 32, 34 are spaced on either side of the wall 30 and extend into section 14 for measuring the differential pressure within the air tube due to a flow of exhaled air.

As shown more clearly in Figure 4 each of the openings 32, 34 is provided with a plug 36, 36' (only one orifice being shown in Figure 4). This plug holds a filter 38 at the interface with hole 28. The filter 38 may be made of a porous material which is permeable to air but impermeable to liquids. In this manner, saliva or other materials from the exhaled air of a person will be limited to the tube and will not contaminate the remainder of the spirometer 10. Furthermore since filter 38 is impermeable to water the spirometer may be immersed in or sprayed with water for cleaning and sanitary purposes. Filter 38 maybe made for example of a hydrophobic filter media such as a 1/16" thick hydrophobic polyethylene with a 10 micron pore size, and about 40% porosity.

As shown more clearly in Figure 5, the plugs are connected by two tubes 40, 42 to a differential pressure transducer 44, which may be for example a MPX 2010D made by Motorola.

The transducer 44 generates an electrical signal on a pair of output wires 46, which signal is proportional to the differential pressure between tubes 40, 42. This signal is amplified by a differential amplifier stage 48 and fed into an analog-to-digital converter 50 which converts the amplifier output into digital signals. The converter output is fed to a microprocessor 52. The microprocessor 52 uses an algorithm stored in a ROM 54 to perform several calculations on the signal from converter 50, and to display the results (i.e. volume and rate of flow) on display 24. Switch 22 activated by button 22' initiates the operation of spirometer 10 through microprocessor 52. The results obtained during each measurement may be stored in a RAM 56 for future reference. An input/output port 58 may also be provided to allow for changing the programming of the microprocessor. Furthermore the microprocessor may be programmed so that on command it can down-load the results accumulated in RAM 56 through port 58 to a printer or a desk-top computer.

A preferred diagram for implementing the circuit shown in Figure 5 is shown in Figures 6A and 6B. It should be understood that the various circuit elements (such as resistance and capacitance values) are shown in the Figures merely for illustrative purposes and do not limit the scope of this invention in any fashion.

In the embodiment of Figures 6A and 6B, differential air pressure in the air tube is sensed by the pressure transducer 44 schematically shown as a resistive bridge. The output of the transducer is processed by an amplifier analog circuit 48 consisting of amplifiers 60, 62, 64 and 66 which may be, for example, Motorola MC 34074 op amps. These amplifiers are used for a relatively high air flow. For low air flows a further amplifier 68 is also used. The outputs of these amplifiers 66, 68 are fed to a multiple channel A/D converter 50, which may be for example a 68HC68A2 manufactured by RCA Harris. The A/D converter 50 feeds its output to microprocessor 52 which may be for example a MC68HC804C4 made by Motorola. After performing the necessary calculations, the microprocessor 52 displays the results on the LCD screen 24. (Display screen 24 may also include LCD display drivers not shown in the Figures for the sake of convenience).

As shown in Figure 6A, the circuit also includes a power supply 70 which provides the required power to the various circuit elements from a battery 72. The operation of the power supply is also controlled by wires W2, W3 by the microprocessor 52. More particularly, the analog section consisting of the amplifiers, the transducer and the digital-to-analog converter is turned on last (when measurements are started) and turned off first (when the measurements are completed) to conserve power. The power to the display screen is independently controlled. Preferably, the display is on whenever the microprocessor is on.

The spirometer 10 further includes a beeper 80 controlled by the microprocessor for generating audible signals for the user.

A further feature of the invention is an automatic offset compensation circuit consisting of a plurality of resistors 74 and an amplifier 76. The resistors 74 are coupled to microprocessor 52 by a plurality of lines 78. This offset compensation circuit operates as follows. During the initialization of the spirometer (described more fully below), the microprocessor checks the output of the pressure transducer to insure that it essentially corresponds to no air flow. If the transducer output is non-zero (due for example to a temperature drift, a variation in the output of the power supply 70, the offset voltages of amplifiers 62, 64, 66, 68 and so on) the microprocessor 52 sends a compensating signal through lines 78 to resistors 74. Resistors 74 and amplifier 76 cooperate in effect to form a digital-to-analog converter used by the microprocessor 52 to produce a DC offset. This DC offset is added by amplifier 62 to the output of transducer 44. During the initialization period when no air is blown through the air tube, the microprocessor sequentially changes the signals on lines 78 until the offset signal from amplifier 76 compensates for the error signal from transducer 44.

OPERATION

The device requires no user adjustment or calibration. To make a measurement, the user pushes the START button 22'. This turns the unit on and initiates a self-test routine. During this self test, all segments on the liquid-crystal display (LCD) are turned on to allow the user to confirm proper operation of the unit. Upon completion of self-test (approximately 5 seconds), the display is blanked except for a READY annunciator: the unit beeps by activity beeper 80 and is now ready for a measurement. The user inhales as much as he can, places his lips around the mouthpiece 26, and blows as hard as possible. The device senses the start of exhalation, measures flow for one second, then displays the volume and maximum rate of air flow for the person (commonly known as FEV_1 and PEFR respectively) measurements on display screen 24.

The parameter FEV_1 and the criteria for measuring this parameter is described in the Official Statement of American Thoracic Society, Medical Section of the American Lung Association --Standardization of Spirometry--1987 Update found in Respiratory Care, November '87, Vol. 32, No. 11, pgs. 1039-1060. The parameter PEFR is identical to the FEF_{max} parameter in the same Statement.

The display will persist for 45 seconds, and then the unit will turn itself off, unless the START button 22' is pushed to initiate another measurement cycle. If no breath is detected within 15 seconds of the READY signal, the unit beeps twice and shuts itself off.

PRINCIPLE OF MEASUREMENT

The spirometer 10 determines the flow rate of air by measuring the differences in pressure developed across a restricting orifice. This pressure difference is related to the flow rate by a well-known equation based on Bernoulli's equation for non-compressible flow. (See for instance Binder, R.C., Fluid Mechanics, 5th Edition, Prentice Hall Inc., Englewood Cliffs, N.J., pgs. 236-237.) In the case of the sharp-edged orifice used in this device, the flow rate is equal to a coefficient (found empirically) multiplied by the square-root of the pressure difference measured between a point upstream of the orifice and a point downstream of the orifice. The value of the coefficient is predominantly determined by the physical design of the device, including the ratio of the area of the flow tube to the area of the orifice, the size of the orifice, and the location of the pressure measurement ports. Ideally, if these physical parameters were held constant, the pressure difference would be dependent only upon the flow rate and density of the fluid being measured. However, there is also some influence of Reynolds Number upon the value of the coefficient, which introduces an error if the coefficient is treated as a constant over a large range of flows.

The pressure difference across the orifice is a function of the square of the flow rate. Therefore, an orifice size must be chosen that does not offer excessive back-pressure to the highest flows to be measured, yet has an adequate, measurable pressure difference at low flow rates.

THEORY OF OPERATION

The air tube 16 contains the sharp-edged orifice (defined by wall 32) that provides a pressure difference which is approximately proportional to the flow rate squared. Preferably, the diameter is about 5/8" and tube 16 has a diameter of about 7/8". This size represents a reasonable compromise between back-pressure at higher flows and at low flows. The outside diameter of the tube 16 is approximately 1", and the length is approximately 3.5". Again, the dimensions represent a compromise; an attempt has been made to keep the overall size small enough to fit a pocket or handbag, yet large enough so that an extraneous mouthpiece is unnecessary. However, a tapered profile is provided on the inlet end of the tube so that a disposable mouthpiece may be added (26' in Figure 1) if desired. The pressure ports are covered with a disk of hydrophobic filter material (as described above) inset flush with the floor of the tube. This material allows air and water vapor to pass freely, but blocks dirt and liquid. It is made of a 1/16" thick rigid plastic and is not easily damaged, allowing the interior of the tube to be cleaned with gently running water or wiped with a soft, lint-free cloth.

The pressure is transmitted via the 1/16" i.d. pipes 40, 42 to the solid-state, piezo-resistive, differential pressure transducer 44. This transducer is provided with a reduced amount of silicon isolation gel coating its diaphragm as compared with the standard transducers used for other measurements. This coating improves the transient response and reduces the sensitivity of the transducer to the position and motion of the spirometer. The differential pressure transducer provides an output signal proportional to the pressure difference between the two openings 32, 34.

The signal from the transducer is amplified and filtered by the 4-stage analog amplifier circuit shown in Figures 6A and 6B. Two outputs are produced by this amplifier circuit. The first circuit generated by amplifier 66 has a total gain of 808. The second circuit generated by amplifier 68 has a total gain of 3,232. The offset voltage of this circuit is adjusted to 300 +/- 50 mV at the first output as described above.

Two filter stages (including amplifiers 64, 66) are included in the analog amplifier circuitry providing a low-pass transfer function with a cut-off frequency of 10hz. The first and second outputs from the analog circuitry are fed to two channels marked CH1, CH3 of the 10-bit A/D converter 50. A signal proportional to the voltage of battery 72 is fed to channel CH2 on the A/D converter 50.

The microprocessor controls all aspects of device function. It is able to independently control power to the display, the pressure transducer and analog circuitry, and itself. Timing pulses are provided by a 3.59 MHz crystal 53. The microprocessor receives the digital values representing pressure, does all necessary calculations, and generates the codes for the liquid-crystal display circuitry.

The liquid-crystal display shows the measured values for FEV_1 and Peak Expiratory Flow Rate (PEFR). It also includes a BATTERY annunciator to indicate when the battery needs replacement and a READY annunciator to indicate when the device is ready to make a measurement.

MEASUREMENT SEQUENCE

The sequence of operation for the spirometer is now described in conjunction with the flow charts of Figures 7A, 7B and 7C. Details of the operations are found in the program listing attached hereto. When the start switch is depressed, the microprocessor 52 is reset and loads its program, which is stored in its Read-Only Memory (ROM) 54. It begins by running a self-test and initialization routine step S1 which checks for internal consistency. It also measures the voltage of battery 72 through input channel CH2 of the A/D converter 52. If the voltage is below a lower limit such that an accurate measurement cannot be made, the microprocessor will not continue. If the voltage is low, but does not exceed this operational limit, the BATTERY annunciator on the LCD is turned on and will not extinguish until the unit turns itself off. If the internal checkout is completed without error, the microprocessor then turns on all segments of the display to allow the user to see if any segments are non-functional. Next, it starts sampling the input on channel CH1 of the A/D converter so as to decide which bits of the digital-to-analog converter (I/O lines 78) to turn on or off and to adjust the offset voltage at channel CH1 to 300 +/- 50 mV. This sequence takes about 2 seconds.

At the end of offset adjustment, the display is blanked (except for the battery annunciator, if voltage is low) and then analog circuitry is allowed to stabilize. The microprocessor in step S2 begins to sample both CH1 and CH3 inputs of the A/D converter signals at a rate of about 100Hz and fills its history array as described below.

The subroutines for step S2 are shown in Figures 7B and 7C. The unit continues to sample both the CH1 and CH4 channels at 100Hz each. It continuously calculates the average and variance of the past four measurements X1, X2, X3 and X4 from the CH3 channel (Steps S21, 22 and 23). It then compares the next sample (X5) to this average and variance in Steps S24, S26. If the current value is higher than the average by more than 2 standard deviations, the unit branches to a start detection routine (Step 27). If the value is more than 2 volts higher than the average, the microprocessor 52 switches over to the CH1 channel (Step 28) and scales the reading (Step 29). If the current value is lower than the average or is less than 2 standard deviations higher than the average, the current value becomes the new 4th sample in the average and variance calculation and the loop continues (Steps 22, 30, 39). This loop will continue for a maximum of 15 seconds. If no start is detected (as described below) in this time, the unit will beep twice and turn itself off in step S8.

If the current sample value is high enough to cause branching to the start detection routine, the old average and variance are saved. In Steps 31, 32 the next sample is now checked to see if it is also above a threshold level 128 (Step 32) or the 2 standard deviation threshold (using either the CH3 or CH1 channel, depending on how large the input on channel CH3 is), and also to see if it is higher than the previous sample (Step 33). If both of these conditions are met, a third sample is obtained and checked in the same way (Step 34). (It must be larger than second sample.) If either the second or third sample fails either test, the average and variance are updated using the new sample values and the program returns to the loop above (Steps 35, 36, 37, 38, 39). If three samples in a row are larger than the threshold value 128 or the average plus 2 standard deviations, and each is larger than the one preceding it, then start is detected (Steps 40, 41, 42, 43). The saved average is stored as the offset to be subtracted from all samples and the 3 samples are converted to flow values and summed as the first three volume increments (Step 41). The actual conversion from the measurement pressure differential samples to volumes is accomplished by using two look-up tables stored in ROM 54. One look-up table correlates samples from the low flow channel CH3 (i.e. 0-2 volts) while the second look-up table correlates the samples from the high flow rate channel CH1 (i.e. 0-4 volts). The values on these look-up tables are determined empirically. As previously mentioned, the orifice used to measure flow rate has a non-linear response, i.e. the pressure differential across the openings 32, 34 due to turbulent flow is non-linear. The present spirometer takes advantage of this non-lineality by separating the pressure differential samples into two ranges based on the flow rate, and then using a look-up table for each. By switching gains, the microprocessor has expanded resolution at low flows. This would be analogous to an equivalent linear range of 16 volts at 10 bits of resolution, or 4 volts at 12 bits of resolution. This feature is made possible by the non-linear characteristic of the orifice. To conserve microprocessor memory space, rather than store a value for every possible A/D code, the microprocessor extrapolates between the two closest stored values. Enough samples are stored to keep the extrapolation error small. In this manner, a less-discriminating (having lower resolution) A/D converter can be used without sacrificing accuracy and sensitivity.

Once start is detected and integration of flow values has begun, the unit begins to look for the maximum slope of the volume curve (step S3). If the slope determined by several consecutive samples is low or negative, the whole measurement is reported as a false start. The maximum positive slope is determined over seven flow samples and, when found, is back extrapolated to determine the start of the first second timing for FEV_1 determination in accordance with the standards set by the American Thoracic Society identified above (step S4). Meantime, each 10 msec. the CH1 and CH3 channels are sampled (step S5). If the CH3 output is less than 2 volts above the offset, it is converted to flow and summed. If the CH3 input is more than 2 volts, the input from channel CH1 is used instead. The unit also looks for, and stores the highest flow sample (step 6).

When the FEV_1 timing has been determined, flow samples have been collected and integrated as volume, and the peak flow value has been stored, the unit displays the measured FEV_1 and PEFR (step S7) and it turns off the analog circuitry to save battery life. The display is maintained for 45 seconds (or until the START button 22' is pushed to initiate another measurement cycle). After 45 seconds, the microprocessor powers down (step S8) to an idle mode.

The operation and circuitry described above and in Figures 6A, 6B and 7 pertain to a basic spirometer. For more advanced modes additional features may be incorporated mostly by modifying the programming of microprocessor 52. For example, before the unit goes into the idle mode, each measurement may be stored into RAM 54 with a time stamp and/or date stamp indicating the time and day on which the measurements were made. The measurements are then recalled and reviewed on the display screen sequentially by activating switch 22. As an incentive, the instantaneous flow measurements could be displayed as the person blows through air tube 26, and when certain mile stones are reached, the beeper could be sounded.

Obviously numerous other modifications can be made to the invention without departing from its scope as defined in the appended claims.

2032796

2500 A.D. 6805 CROSS ASSEMBLER   -   VERSION 3.00c

INPUT FILENAME : STARTRUN.SRC
OUTPUT FILENAME : STARTRUN.OBJ

```
                LIST    ON

        ;###########################################################################
        ;
        ;       SONODYNE AMERICA LIMITED      SPIROMETER PROJECT
        ;
        ;       JUNE 1989                     SOFTWARE 1.0
        ;
        ;...........................................................................
        ;
        ;  STARTRUN.SRC
        ;
        ;  ROUTINE MEASURES THE OFFSET VOLTAGE AND DETECTS WHEN THE USER HAS STARTED
        ;  USES NEW ROUTINE THAT CALCULATES THE VARIANCE OF THE SIGNAL AND DETECTS
        ;  IF THE VALUE IS LARGER THAN THIS VARIANCE
        ;
        ;###########################################################################

        ; DEFINE ENTRY AND EXIT POINTS FOR SUBROUTINES

                GLOBAL     START              ; ROUTINE DETECTS START OF BREATH
                GLOBAL     CAL_VAR            ; CALCULATES VARIENCE

                EXTERNAL   GETDATA            ; GETS DATA FROM SOURCE

                EXTERNAL   DIVIDE
                EXTERNAL   MULTIPLY

        ;...........................................................................

        ; DEFINES AND VARIABLES IN FILE:   DEFINES.SRC

                LIST       OFF


                LIST       ON

        ;...........................................................................

        ;  MODIFICATIONS



        ;###########################################################################

        ; NOTE  THE ROUTINE  GETDATA IS KEEPING HISTORY INFORMATION IN THE OFFSET
```

```
                        ; VOLTAGE

                        ;..............................................................................


                        ; MAIN LOOP    GETS VALUE, CALCULATES STATISTICS AND TESTS,  USER MUST
                        ;   START IN 15 SECONDS, OTHERWISE IT BEEPS AND TURNS OFF

0000   3F 66            START    CLR       FCOUNT              ; CLEAR LOOP COUNTER
0002   3F 67                     CLR       NEG_SLOP

                        ;. . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . .

0004   CD 00 00         MAINLOOP JSR       GETDATA             ; GET AN INPUT VALUE OF VOLTAGE


                        ; TEST IF VOLT#4 TOO BIG AND IF SO, USE VOLT#1 (GAIN 1)

0007   B6 AE                     LDA       VOLT4LO             ; TEST RAW VOLTAGE FROM SENSOR
0009   A0 00                     SUB       #$00
000B   B6 AF                     LDA       VOLT4HO
000D   A2 02                     SBC       #$02

000F   25 10                     BCS       VALU_OK             ; BRANCH AND USE GAIN 4 VALUES

0011   B6 A1                     LDA       VOLT1L_O
0013   B7 AE                     STA       VOLT4LO
0015   B6 C7                     LDA       VOLT1H_O
0017   B7 AF                     STA       VOLT4HO

0019   38 AE                     LSL       VOLT4LO             ; MULTIPLY BY 4 TO OFFSET FOR GAIN OF
001B   39 AF                     ROL       VOLT4HO             ; 4
001D   38 AE                     LSL       VOLT4LO
001F   39 AF                     ROL       VOLT4HO



                        ;. . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . .

0021   3D 66            VALU_OK  TST       FCOUNT              ; TEST COUNT OF POSITIVE ATTEMPTS
0023   27 03                     BEQ       CAL_STAT            ; ZERO, CALCULATE STATISTICS
0025   CC 00 8A                  JMP       DETECTED            ; FOUND ONE ALREADY, TEST THIS INPUT


                        ;..............................................................................

                        ; FIRST CALCULATE THE VARIENCE (# 4[illegible]) OF PREVIOUS 4 SAMPLES

0028   CD 01 0F         CAL_STAT JSR       CAL_VAR             ; RETURNS VARIANCE

                        ;. . TEST IF ZERO, IF SO SET TO MINIMUM VALUE

002B   3D 86                     TST       VARNCE_H
002D   26 0C                     BNE       TEST_IT
002F   B6 85                     LDA       VARNCE_L            ; TEST IF LESS THAN
0031   A0 10                     SUB       #16
0033   25 02                     BCS       SET_LOW
0035   20 04                     BRA       TEST_IT
```

```
0037   A6 10     SET_LOW  LDA    #10
0039   B7 85              STA    VARNCE_L


                 ;. . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . .

                 ;. . . TEST IF BREATH STARTED - IS RESIDUAL OF VOLTO IS GREATER THAN VARIANCE

                 ; FIRST TEST IF CHANGE IS AN INCREASE IN VOLTAGE - LARGER THAN OFFSET

003B   B6 87     TEST_IT  LDA    AVG_OFFL          ; GET AVERAGE OFFSET AND
003D   B0 AE              SUB    VOLT4LO           ; SUBTRACT NEW VOLTAGE
003F   B7 72              STA    TEMPL
0041   B6 88              LDA    AVG_OFFH
0043   B2 AF              SBC    VOLT4HO
0045   B7 71              STA    TEMPH

0047   24 29              BCC    NEGSLOP           ; NEW VOLTAGE SMALLER OR EQUAL


                 ;. . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . .

                 ;. . TEST IF LARGER THAN VARIANCE - CALCULATE RESIDUAL VALUE . . . . . . . . .

0049   3F 67              CLR    NEG_SLOP          ; CLEAR NEG SLOPE COUNTER

004B   B6 AE              LDA    VOLT4LO           ; (VOLTO - AVG OFFSET)**2
004D   B7 72              STA    TEMPL
004F   B6 AF              LDA    VOLT4HO
0051   B7 71              STA    TEMPH
0053   CD 01 BF           JSR    DELTASQ           ; RETURNS RESIDUAL IN FLOWH,L

0056   B6 85              LDA    VARNCE_L          ; IS RESIDUAL > 4*VARIANCE
0058   B0 74              SUB    FLOWL             ; BY: 4*VARIANCE - RESIDUAL
005A   B6 86              LDA    VARNCE_H
005C   B2 73              SBC    FLOWH

005E   24 0D              BCC    NOT_OK            ; RESULT ZERO OR POSITIVE

0060   3C 66     OK_VAL   INC    FCOUNT            ; OK. VALUE LARGER, ADVANCE COUNT
0062   B6 74              LDA    FLOWL             ; SAVE RESIDUAL FOR TESTING NEXT PERIOD
0064   B7 85              STA    VARNCE_L
0066   B6 73              LDA    FLOWH
0068   B7 86              STA    VARNCE_H
006A   CC 00 D2           JMP    TESTIME           ; GO TO TEST IF TIME UP


006D   3F 66     NOT_OK   CLR    FCOUNT            ; RESET COUNT AND
006F   CC 00 D2           JMP    TESTIME


                 ;. . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . .

                 ;. . NEGATIVE SLOPE DETECTED. TEST IF 4 SLOPES IN A ROW AND THEN ASSUME . . .
                 ;    UNIT IN MOTION. RETURN WITH FALSE START CODE

0072   3F 66     NEGSLOP  CLR    FCOUNT            ; RESET COUNT
```

```
                               ; TEST IF DIFFERENCE IS GREATER THAN 4

0074   B6 72                          LDA      TEMPL
0076   A0 04                          SUB      #04
0078   25 0B                          BCS      SKIPCNT

007A   3C 67                          INC      NEG_SLOP          ; ADVANCE COUNT

007C   B6 67                          LDA      NEG_SLOP          ; TEST IF X TIMES IN A ROW
007E   A1 04                          CMP      #4
0080   26 05                          BNE      EXITIT

0082   AE 01                          LDX      #$01              ; RETURN WITH ERROR CODE
0084   81                             RTS

0085   3F 67                 SKIPCNT  CLR      NEG_SLOP          ; RESET COUNT
0087   CC 00 02              EXITIT   JMP      TESTIME           ; GO TO TEST IF TIME UP



                               ;.........................................................................

                               ; . PREVIOUS TIME PERIODS SUCCESSFUL, TRY NEXT N TIMES . . . . . . . . . . . . . .

                               ; FIRST TEST IF VOLTAGE VALUE (FLOWRATE) IS VERY LARGE: > 128 A/D UNITS

008A   B6 AE                 DETECTED LDA      VOLT4LO           ; SUBTRACT VOLT FROM AVERAGE OFFSET
008C   B0 37                          SUB      AVG_OFFL
008E   B7 72                          STA      TEMPL             ; SAVE RESULT
0090   B6 AF                          LDA      VOLT4HO
0092   B2 38                          SBC      AVG_OFFH
0094   B7 71                          STA      TEMPH

0096   B6 72                          LDA      TEMPL             ; TEMP - 128
0098   A0 80                          SUB      #128
009A   B6 71                          LDA      TEMPH
009C   A2 00                          SBC      #00

009E   24 1A                          BCC      BIGGER            ; THE VOLTAGE FROM THE SENSOR IS VERY
                                                                 ; BIG SO ASSUME IT IS ALSO LARGER
                                                                 ; THAN THE VARIANCE


                               ;. . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . . .

                               ; SENSOR VOLTAGE SMALL SO CALCULATE THE RESIDUAL

00A0   B6 AE                 VAL_OK   LDA      VOLT4LO           ; CALCULATE RESIDUAL OF NEW DATA
00A2   B7 72                          STA      TEMPL
00A4   B6 AF                          LDA      VOLT4HO
00A6   B7 71                          STA      TEMPH
00A8   CD 01 8F                       JSR      DELTASQ           ; (VOLTO - AVE OFFSET)**2, (FLOWL,H)


                               ; . . . TEST IF LARGER THAN RESIDUAL OF THE PREVIOUS TIME PERIOD

00AB   B6 85                          LDA      VARNCE_L          ; NEW VALUE - OLD VALUE
```

```
00AD  B0 74                 SUB     FLOWL
00AF  B6 86                 LDA     VARNCE_H
00B1  B2 73                 SBC     FLOWH

00B3  25 05                 BCS     BIGGER          ; BRA IF NEW VALUE > OLD VALUE


                    ;. EQUAL OR SMALLER SO RESET AND GO UPDATE THE STATISTICS . . . . . . . . . .

00B5  3F 66                 CLR     FCOUNT          ; CLEAR COUNTER
00B7  CC 00 28              JMP     CAL_STAT        ; AND CALCULATE STATISTICS FOR THIS
                                                    ; TIME PERIOD



                    ;. . . . . . . . . . . . . . . . . . . . . . . . .

                    ;. . . VALUE LARGER ON THIS TRY SO TEST IF DONE. . . . . . . . . . . . . . . .

00BA  3C 66         BIGGER  INC     FCOUNT
00BC  B6 66                 LDA     FCOUNT          ; TEST IF DONE
00BE  A1 03                 CMP     #03
00C0  27 0B                 BEQ     RESET

                    ; NOT DONE, SAVE THE PRESENT RESIDUAL FOR NEXT CHECK . . . . . . . . . . . .

00C2  B6 74                 LDA     FLOWL
00C4  B7 85                 STA     VARNCE_L
00C6  B6 73                 LDA     FLOWH
00C8  B7 86                 STA     VARNCE_H

00CA  CC 00 D2              JMP     TESTIME         ; EXIT AND TEST IF TIMER DONE


00CD  3F 66         RESET   CLR     FCOUNT
00CF  CC 00 DE              JMP     CAL_VOL         ; DONE - CALCULATE VOLUME NEXT


                    ;.....................................................................

                    ; TEST TIMER FOR 15 SEC UP

00D2  B6 51         TESTIME LDA     ON_TIME         ; TEST ON TIME TO BE 45 SECONDS OR LESS
00D4  A0 2D                 SUB     #45
00D6  25 03                 BCS     TIM_OUT         ; TIME UP, EXIT ROUTINE
00D8  CC 00 04              JMP     MAINLOOP        ; LOOP BACK AND RETRY

00DB  AE 00         TIM_OUT LDX     #$00
00DD  81                    RTS                     ; EXIT SYSTEM WITH ERROR = 0



                    ;!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!

                    ; START DETECTED, CALCULATE START TIME AND TOTAL VOLUME

00DE  1A 75         CAL_VOL BSET    STARTED,FLAGS   ; SET BREATH STARTED FLAG
```

```
00E0   34 93                LSR     FLOW_M3H        ; CALCULATE FM3/2
00E2   36 94                ROR     FLOW_M3L

00E4   B6 94                LDA     FLOW_M3L        ; ADD IN FM2
00E6   BB 92                ADD     FLOW_M2L
00E8   B7 77                STA     VOLUMEL
00EA   B6 93                LDA     FLOW_M3H
00EC   B9 91                ADC     FLOW_M2H
00EE   B7 76                STA     VOLUMEH

00F0   B6 77                LDA     VOLUMEL         ; ADD IN FM1
00F2   BB 90                ADD     FLOW_M1L
00F4   B7 77                STA     VOLUMEL
00F6   B6 76                LDA     VOLUMEH
00F8   B9 8F                ADC     FLOW_M1H
00FA   B7 76                STA     VOLUMEH

00FC   B6 8D                LDA     FLOW_OH         ; CALCULATE FLOW/2
00FE   44                   LSRA
00FF   97                   TAX                     ; AND SAVE IN X REGISTER
0100   B6 8E                LDA     FLOW_OL
0102   46                   RORA

0103   BB 77                ADD     VOLUMEL         ; ADD TO VOLUME
0105   B7 77                STA     VOLUMEL
0107   9F                   TXA
0108   B9 76                ADC     VOLUMEH
010A   B7 76                STA     VOLUMEH

010C   AE 02                LDX     #$02            ; EXIT WITH OK CODE

010E   81           DONE    RTS                     ; AND EXIT "START"




                    ;#########################################################################

                    ;........ CALCULATE OFFSET AVERAGE AND VARIANCE STATISTIC .....................

                    ;. . FIRST CALCULATE AVERAGE OFFSET

010F   B6 B0        CAL_VAR LDA     VOLT4L1         ; CALCULATE AVERAGE OFFSET VALUE
0111   BB B2                ADD     VOLT4L2         ; V1 + V2 + V3 + V4
0113   B7 87                STA     AVG_OFFL
0115   B6 B1                LDA     VOLT4H1
0117   B9 B3                ADC     VOLT4H2
0119   B7 88                STA     AVG_OFFH

011B   B6 87                LDA     AVG_OFFL
011D   BB B4                ADD     VOLT4L3
011F   B7 87                STA     AVG_OFFL
0121   B6 88                LDA     AVG_OFFH
0123   B9 B5                ADC     VOLT4H3
0125   B7 88                STA     AVG_OFFH

0127   B6 87                LDA     AVG_OFFL
```

```
0129  BB B6        ADD   VOLT4L4
012B  B7 87        STA   AVG_OFFL
012D  B6 88        LDA   AVG_OFFH
012F  B9 B7        ADC   VOLT4H4
0131  B7 88        STA   AVG_OFFH

0133  34 88        LSR   AVG_OFFH        ; DIVIDE BY 4
0135  36 87        ROR   AVG_OFFL
0137  34 88        LSR   AVG_OFFH
0139  36 87        ROR   AVG_OFFL

             ;. . CALCULATE VARIANCE VALUE . . . . . . . . . . . . . . . . . . . . . . .

013B  B6 B0        LDA   VOLT4L1         ; CALCULATE (VOLT1-OFFSET)**2
013D  B7 72        STA   TEMPL
013F  B6 B1        LDA   VOLT4H1
0141  B7 71        STA   TEMPH
0143  CD 01 BF     JSR   DELTASQ
0146  B6 74        LDA   FLOWL
0148  B7 85        STA   VARNCE_L
014A  B6 73        LDA   FLOWH
014C  B7 86        STA   VARNCE_H

014E  B6 B2        LDA   VOLT4L2         ; CALCULATE (VOLT2-OFFSET)**2
0150  B7 72        STA   TEMPL
0152  B6 B3        LDA   VOLT4H2
0154  B7 71        STA   TEMPH
0156  CD 01 BF     JSR   DELTASQ
0159  B6 74        LDA   FLOWL
015B  BB 85        ADD   VARNCE_L
015D  B7 85        STA   VARNCE_L
015F  B6 73        LDA   FLOWH
0161  B9 86        ADC   VARNCE_H
0163  B7 86        STA   VARNCE_H

0165  B6 B4        LDA   VOLT4L3         ; CALCULATE (VOLT3-OFFSET)**2
0167  B7 72        STA   TEMPL
0169  B6 B5        LDA   VOLT4H3
016B  B7 71        STA   TEMPH
016D  CD 01 BF     JSR   DELTASQ
0170  B6 74        LDA   FLOWL
0172  BB 85        ADD   VARNCE_L
0174  B7 85        STA   VARNCE_L
0176  B6 73        LDA   FLOWH
0178  B9 86        ADC   VARNCE_H
017A  B7 86        STA   VARNCE_H

017C  B6 B6        LDA   VOLT4L4         ; CALCULATE (VOLT4-OFFSET)**2
017E  B7 72        STA   TEMPL
0180  B6 B7        LDA   VOLT4H4
0182  B7 71        STA   TEMPH
0184  CD 01 BF     JSR   DELTASQ
0187  B6 74        LDA   FLOWL
0189  BB 85        ADD   VARNCE_L
018B  B7 85        STA   VARNCE_L
018D  B6 73        LDA   FLOWH
018F  B9 86        ADC   VARNCE_H
```

```
0191    B7 86                   STA     VARNCE_H


                        ;. . TEST IF ZERO AND AND IF SO EXIT

0193    3D 85                   TST     VARNCE_L
0195    26 06                   BNE     MATH_43
0197    3D 86                   TST     VARNCE_H
0199    26 02                   BNE     MATH_43
019B    20 21                   BRA     DONE_CAL

                        ; . . . MULTIPLY BY 4 AND DIVIDE BY 3

019D    38 85           MATH_43 LSL     VARNCE_L        ; MULTIPLY BY 4
019F    39 86                   ROL     VARNCE_H
01A1    38 85                   LSL     VARNCE_L
01A3    39 86                   ROL     VARNCE_H

01A5    B6 85                   LDA     VARNCE_L
01A7    B7 72                   STA     TEMPL
01A9    B6 86                   LDA     VARNCE_H
01AB    B7 71                   STA     TEMPH

01AD    A6 03                   LDA     #3              ; SET UP DIVISOR
01AF    B7 63                   STA     DIVSORL
01B1    3F 62                   CLR     DIVSORH

01B3    CD 00 00                JSR     DIVIDE          ; DO THE DIVISON

01B6    B6 72                   LDA     TEMPL           ; RESTORE VALUE IN VARANCE
01B8    B7 85                   STA     VARNCE_L
01BA    B6 71                   LDA     TEMPH
01BC    B7 86                   STA     VARNCE_H

01BE    81              DONE_CAL RTS                    ; AND EXIT "CAL_VAR"


                        ;.........................................................................

                        ; SUBROUTINE TO CALCULATE  (VOLT - VAVG)**2     " CALLED THE RESIDUAL "
                        ; USES MULTIPLY ROUTINE,  ANSWER RETURNED IN "FLOWH,FLOWL"

01BF    B6 72           DELTASQ LDA     TEMPL           ; SUBTRACT VOLT FROM AVERAGE OFFSET
01C1    B0 87                   SUB     AVG_OFFL
01C3    B7 72                   STA     TEMPL           ; SAVE RESULT
01C5    B6 71                   LDA     TEMPH
01C7    B2 88                   SBC     AVG_OFFH
01C9    B7 71                   STA     TEMPH

01CB    B6 72                   LDA     TEMPL           ; TEST FOR ZERO RESULT
01CD    26 09                   BNE     NOT_ZERO
01CF    B6 71                   LDA     TEMPH
01D1    26 05                   BNE     NOT_ZERO

01D3    3F 74                   CLR     FLOWL           ; OUTPUT A ZERO RESULT
01D5    3F 73                   CLR     FLOWH
01D7    81                      RTS                     ; AND EXIT
```

```
                                 ;. . . . . . . . . . . . . . . . . . . . . . . . .

01D8   3D 71         NOT_ZERO TST      TEMPH            ; TEST IF POSITIVE AND CONTINUE
01DA   2A 04                  BPL      OK_CAL

01DC   33 72                  COM      TEMPL            ; NEG: CONVERT TO POSITIVE VALUE
01DE   33 71                  COM      TEMPH

01E0   B6 72         OK_CAL   LDA      TEMPL
01E2   B7 74                  STA      FLOWL
01E4   B6 71                  LDA      TEMPH
01E6   B7 73                  STA      FLOWH

01E8   CD 00 00               JSR      MULTIPLY         ; CALCULATE SQUARE OF DIFFERENCE
                                                        ; RESULT IN FLOWH,L

01EB   81                     RTS                       ; EXIT 'DELTASQ'

                     ;..................................................................

                              LIST     OFF
```

LINES ASSEMBLED :   829   ASSEMBLY ERRORS :   0

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A portable spirometer comprising:
a housing;
an air tube coupled to said housing and including a substantially linear air passage with a reduced diameter orifice for generating a turbulence in the air passage;
pressure sensing means for sensing a differential pressure across said orifice when a person exhales through said air tube;
filter means disposed at an interface between said tube and said pressure sensing means for protecting said pressure sensing means, said filter means being made of a material permeable to gases and impermeable to liquids;
electronic circuitry means disposed in said housing and coupled to said pressure sensing means for generating electric input signals corresponding to said differential pressure, said electronic circuitry means including calculating means for calculating performance signals from said electric input signals; and
display means for displaying said performance signals.

2. The spirometer of claim 1, wherein said pressure sensing means includes:
access holes disposed in said air tube and spaced from said orifice; and

transducer means coupled to said access holes for generating a transducer output corresponding to said differential pressure.

3. The spirometer of claim 1 or 2, further comprising power supply means disposed in said housing for supplying said circuitry means with electrical power, said circuitry means deactivating said power supply means when said spirometer is in an idle mode.

4. The spirometer of claim 3, wherein said electronic circuitry means includes analog circuit means and digital circuit means, and wherein said power supply means provides power to said analog circuit means when said spirometer is not in said idle mode.

5. The spirometer of claim 3, wherein said power supply means includes a battery to make said spirometer self-contained.

6. The spirometer of any one of claims 1 to 5, further comprising voltage offset compensation means for offsetting voltage offsets in said circuitry means.

7. The spirometer of claim 6, wherein said voltage offset compensation means includes digital-to-analog convertor means for receiving an error signal from said means corresponding to said voltage offset and said converter means generating a convertor output.

8. The spirometer of any one of claims 1 to 7, wherein said electronic circuitry means includes:
first amplifier means for amplifying said electric input signals by a first factor to generate a first amplified output;
second amplifier means for amplifying said electric input signals by a second factor to generate a second amplified output; and
microprocessor means being coupled to first and second amplified output, said microprocessor means being programmed to select one of said first and second amplified outputs to calculate said performance signals.

9. The spirometer of claim 8, wherein said electronic circuitry means further includes analog-to-digital converter means for converting said first and second amplified output for said microprocessor means.

10. The spirometer of claim 8 or 9, wherein said air passage has a non-linear response to air flow;
wherein said microprocessor means includes select means which selects said first amplified output in response to a first air flow below a threshold level; and
wherein said select means selects said second amplified output in response to a high air flow above said threshold level.

11. The spirometer of claim 8, 9 or 10, wherein said microprocessor means includes sampling means which samples the air flow through said air passage and which calculates a running average signal.

12. The spirometer of claim 11, wherein said microprocessor means includes monitoring means which monitors said average signal to discriminate a test from noise.

2032796

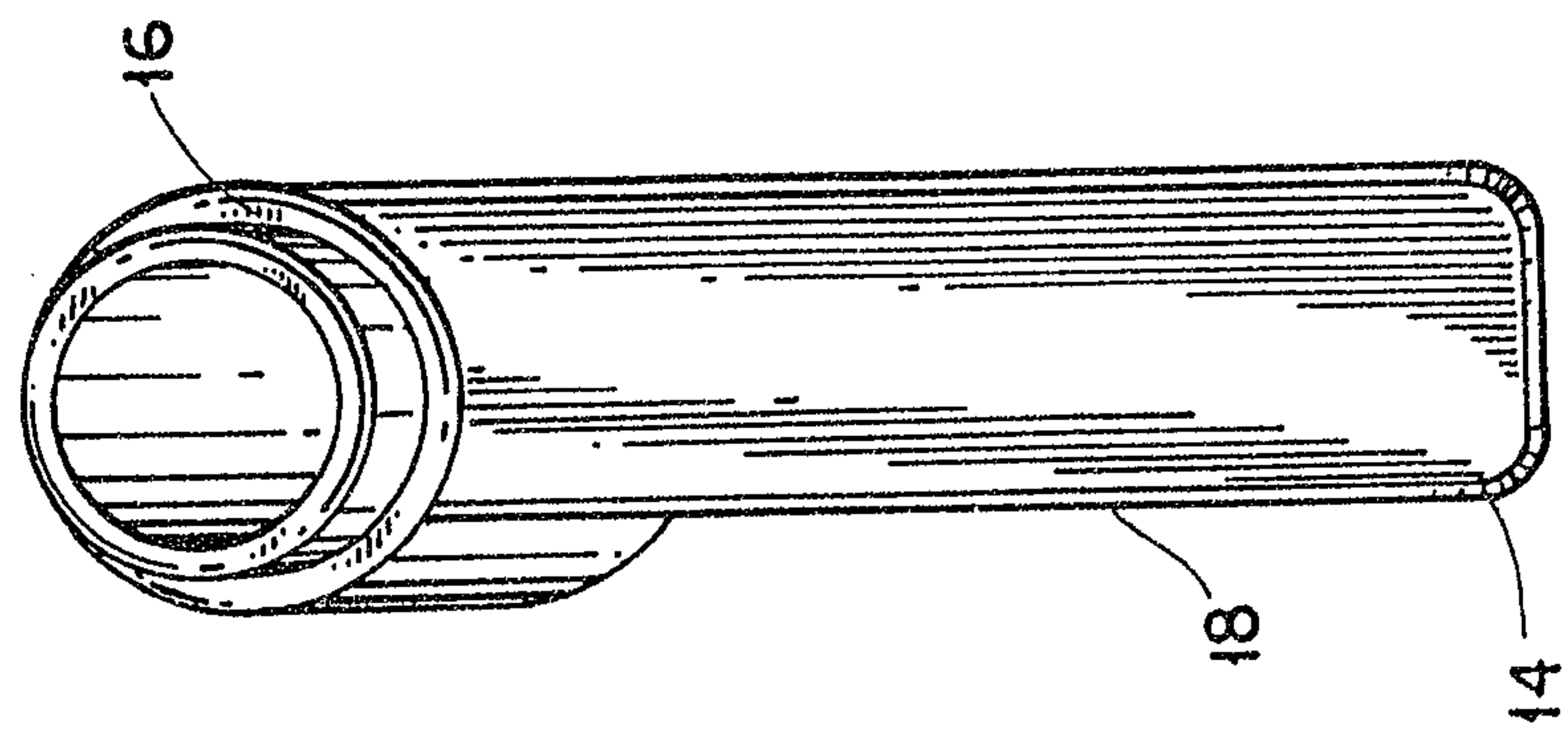


FIG. 2

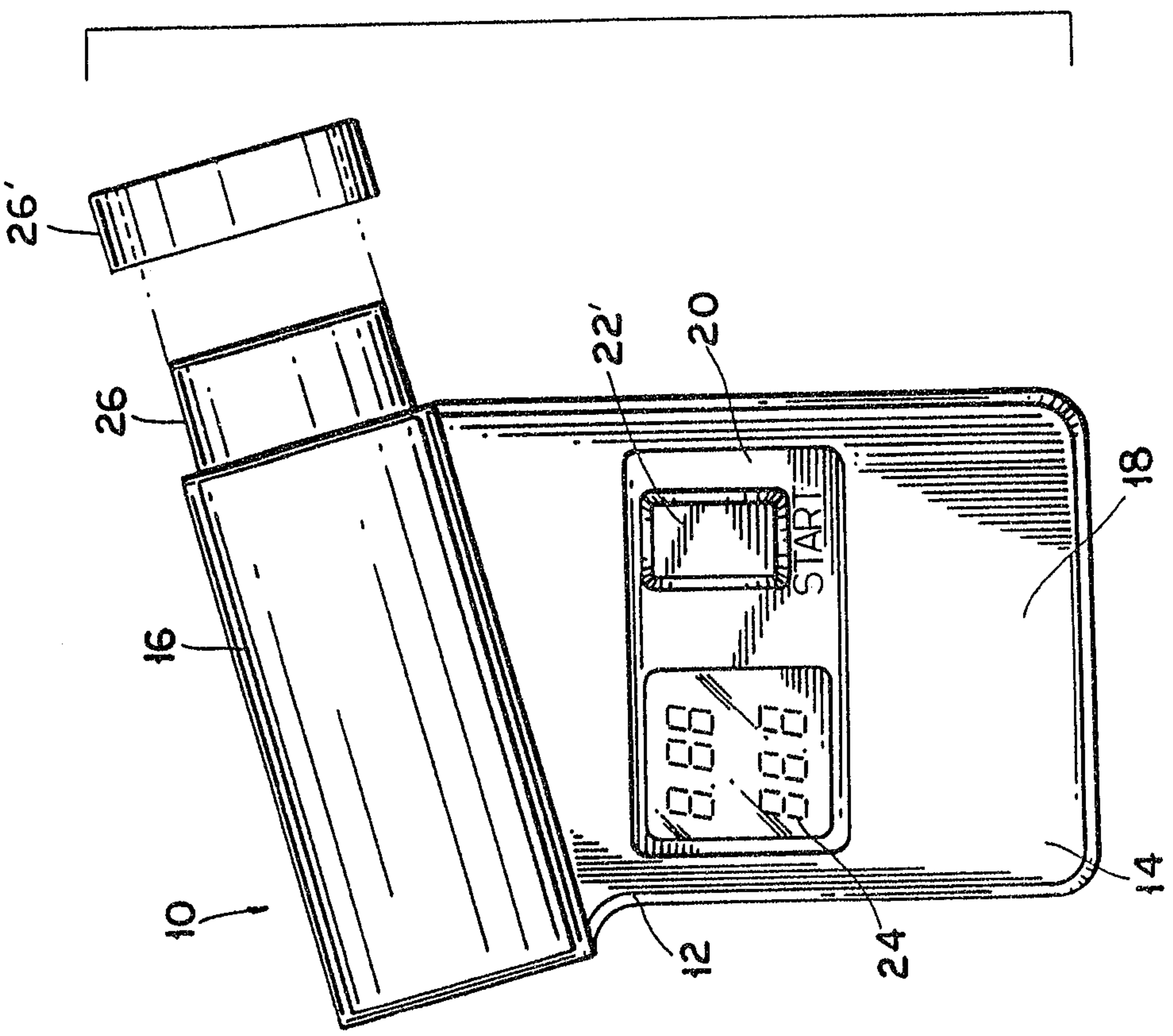


FIG. 1

Marks & Clerk

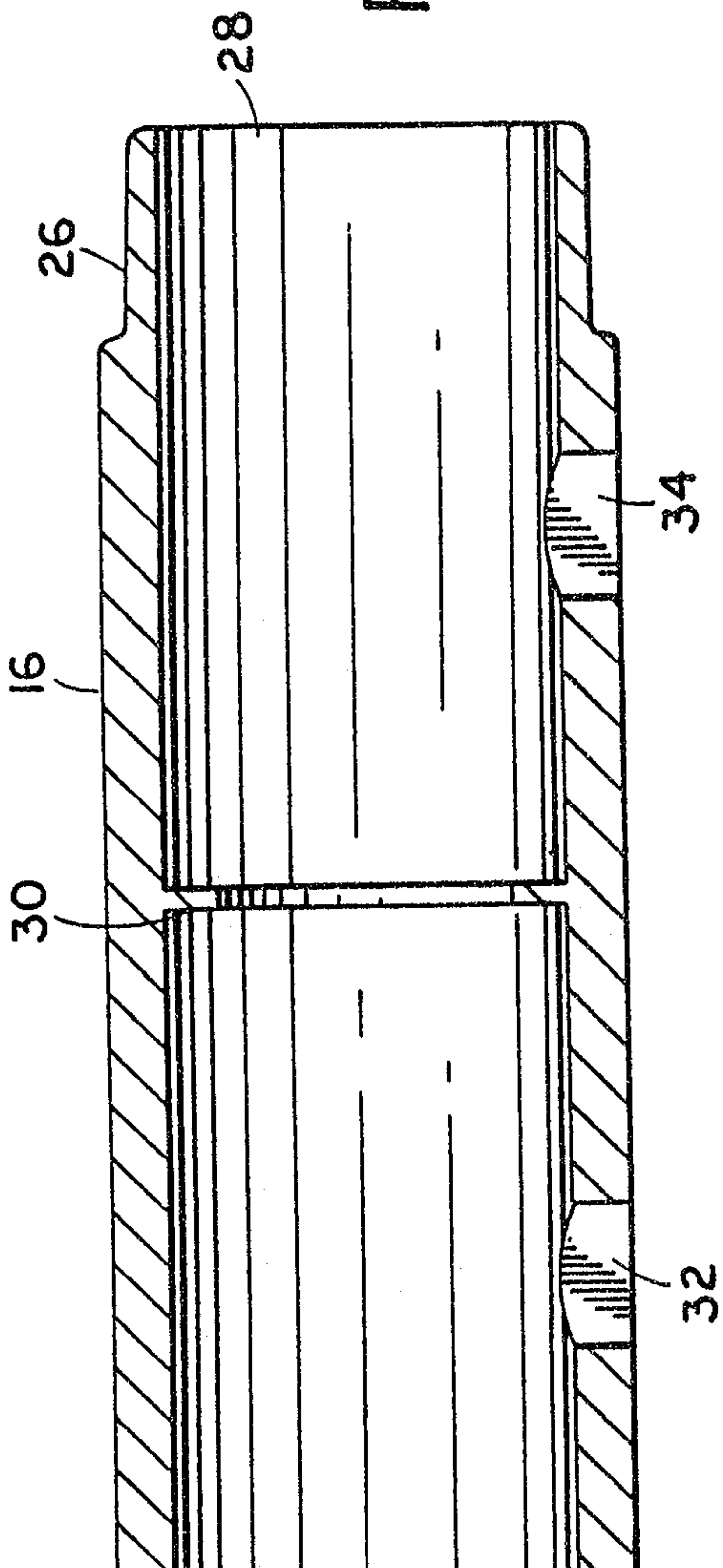


FIG. 3

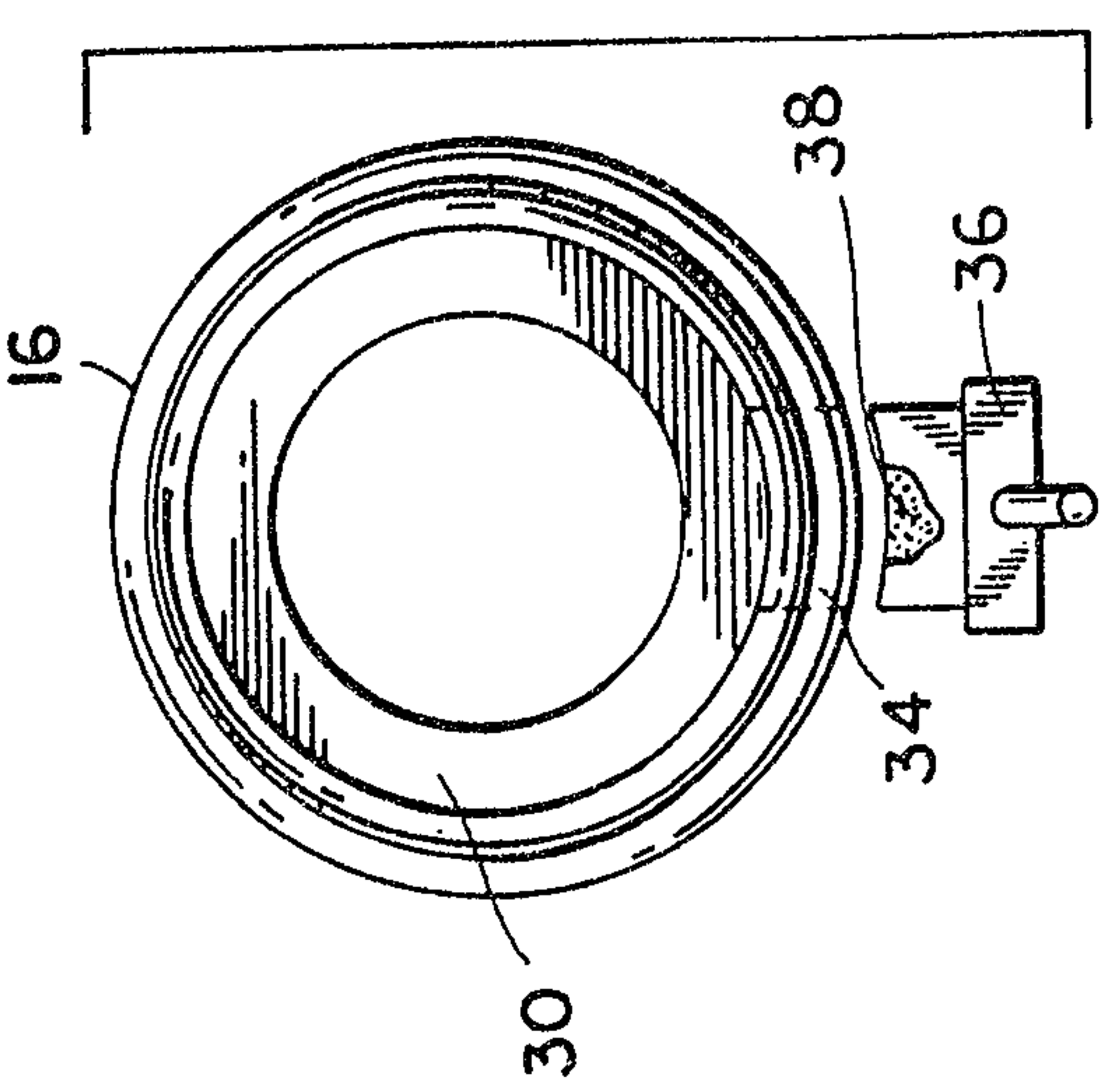


FIG. 4

Marks & Clerk

2032796

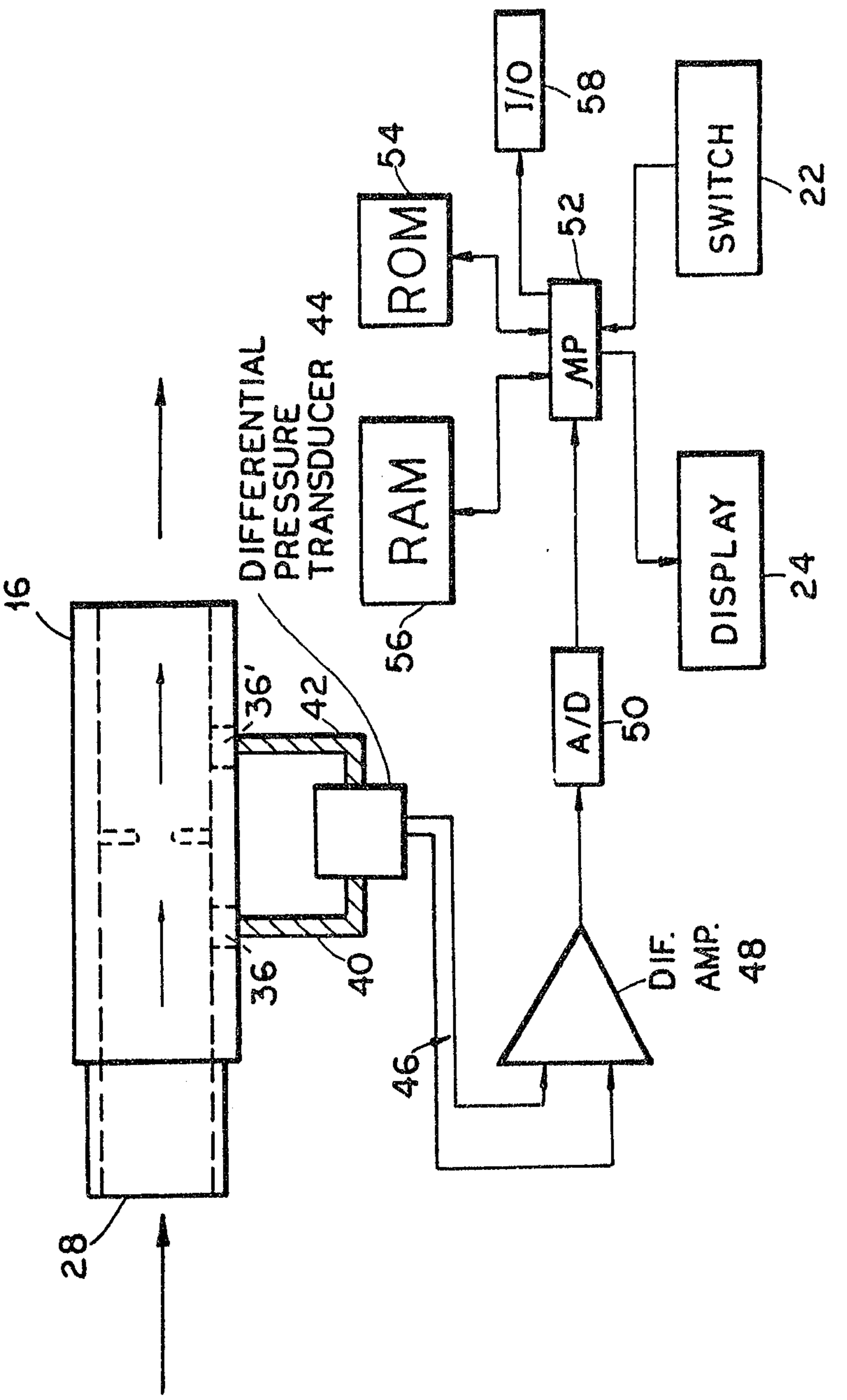


FIG. 5

Marks & Clerk

2032796

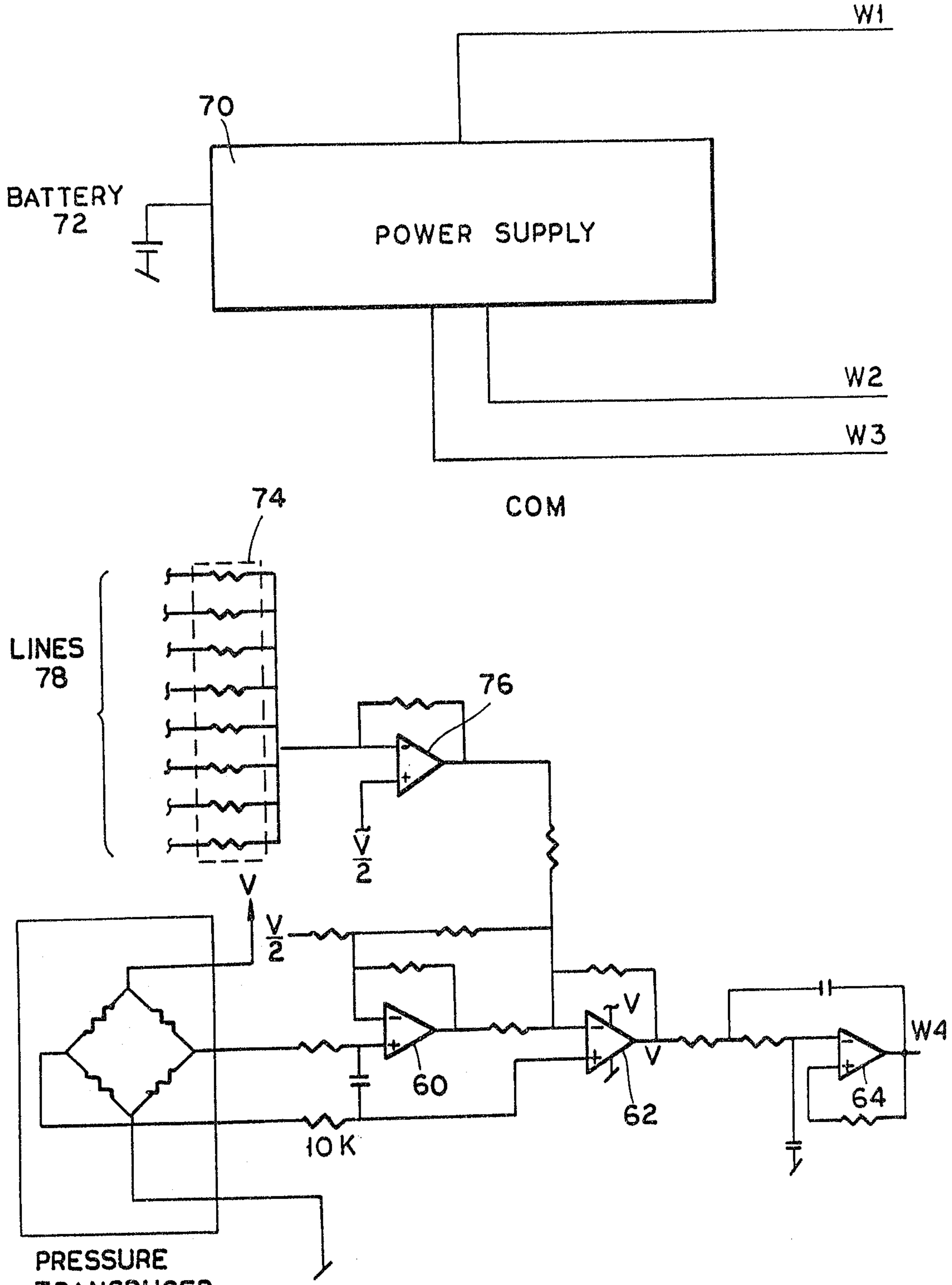


FIG. 6A

Marks & Clerk

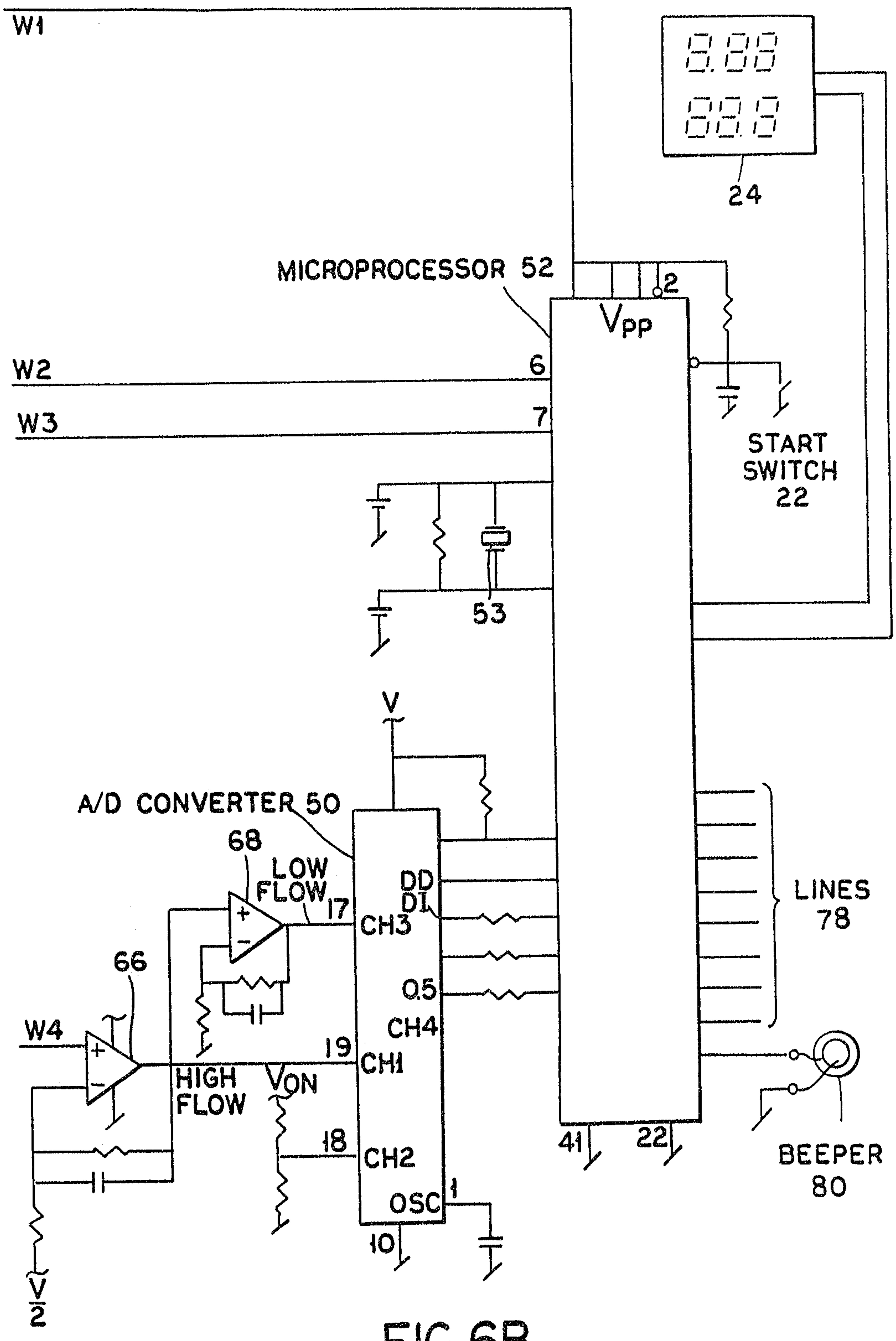


FIG. 6B

Marks & Clerk

SYSTEM FLOWCHART

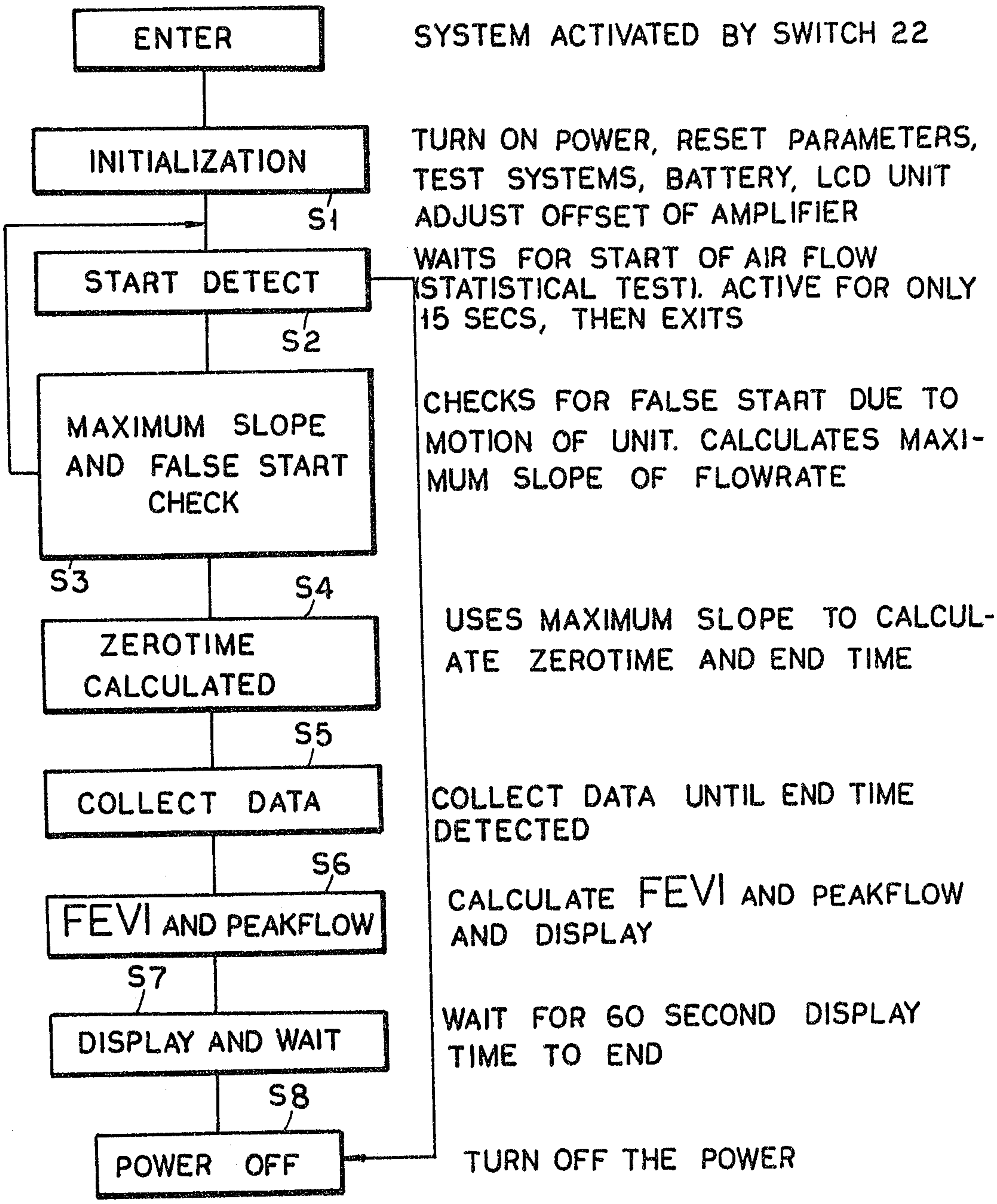


FIG. 7A

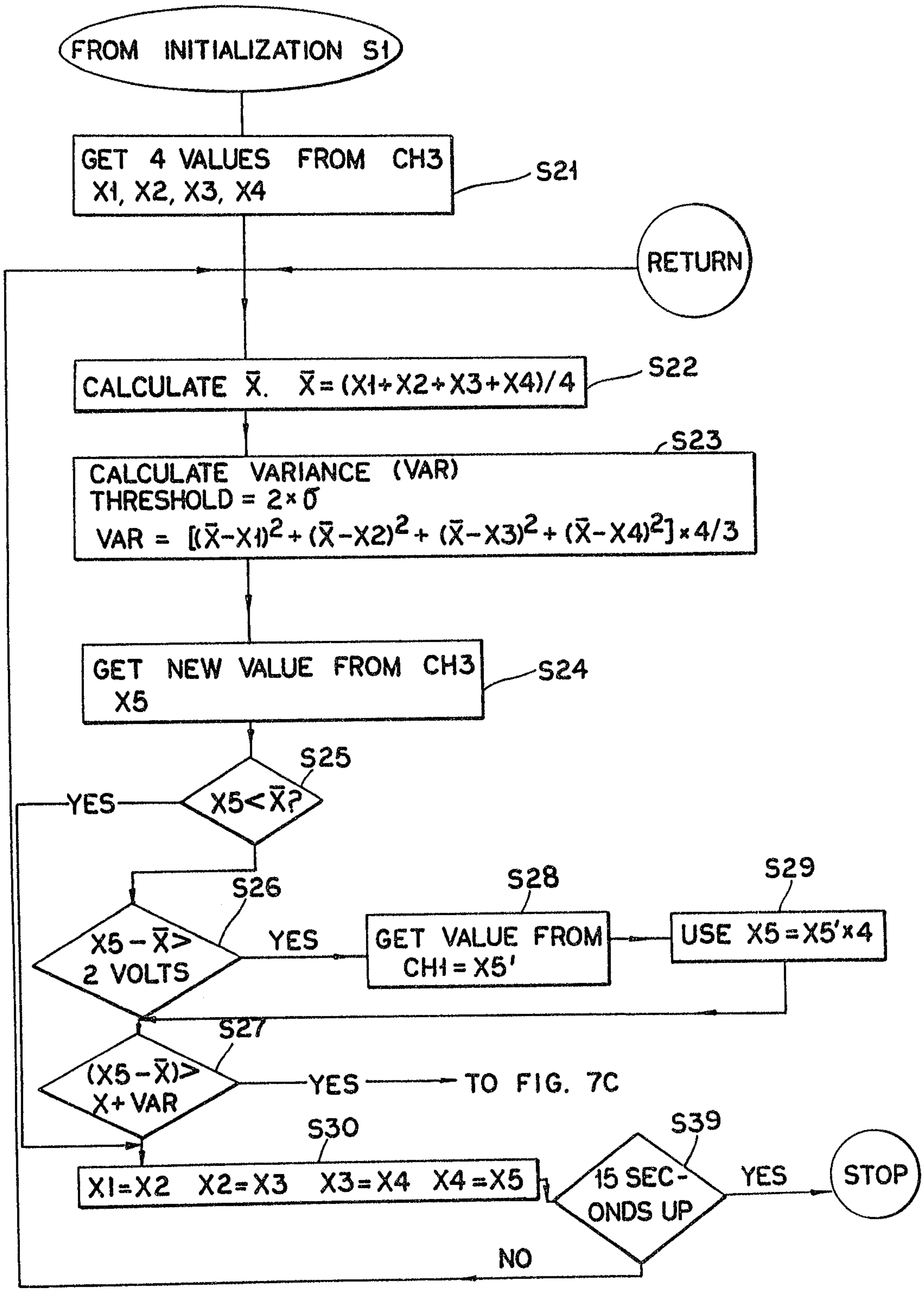
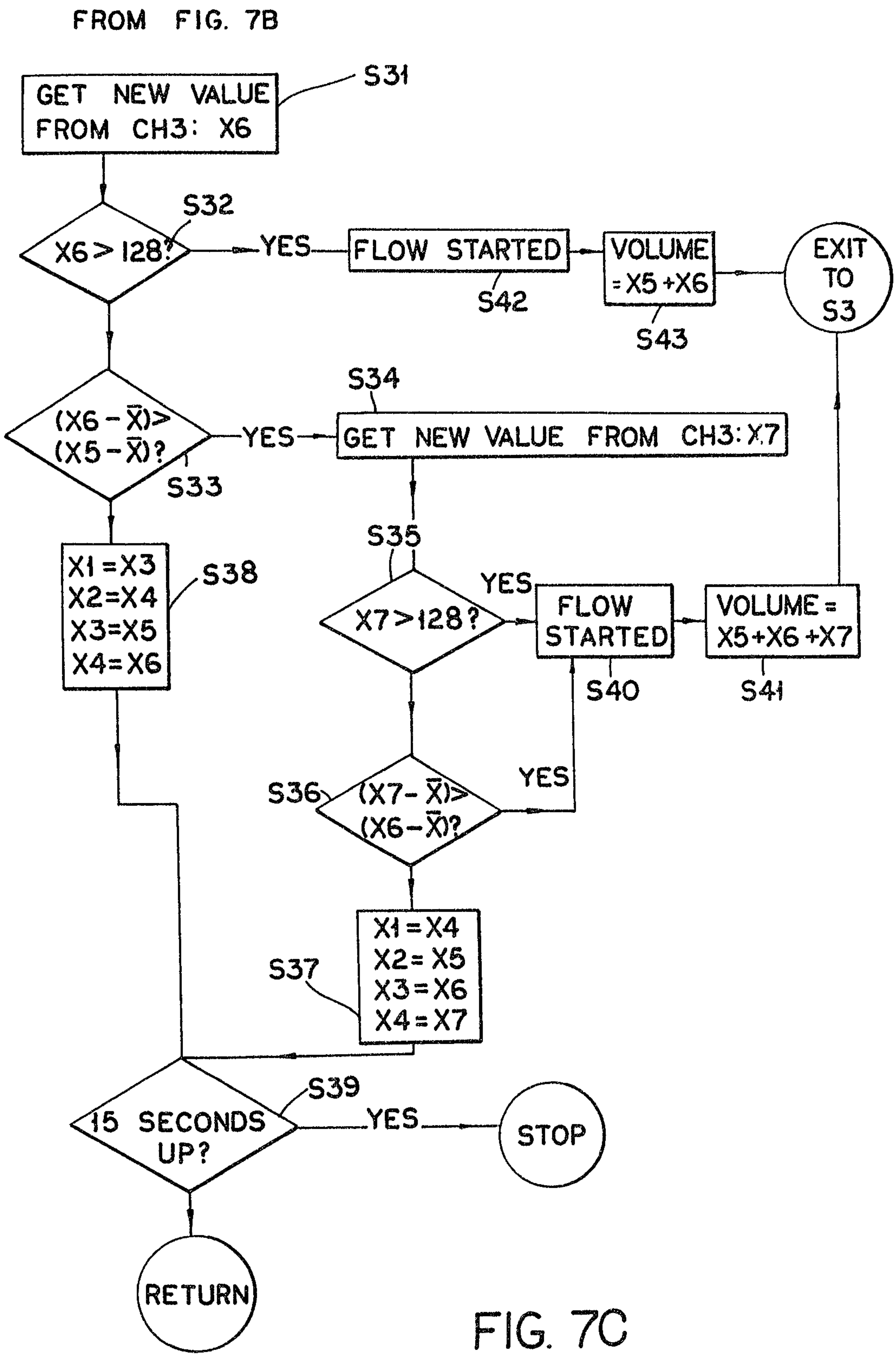
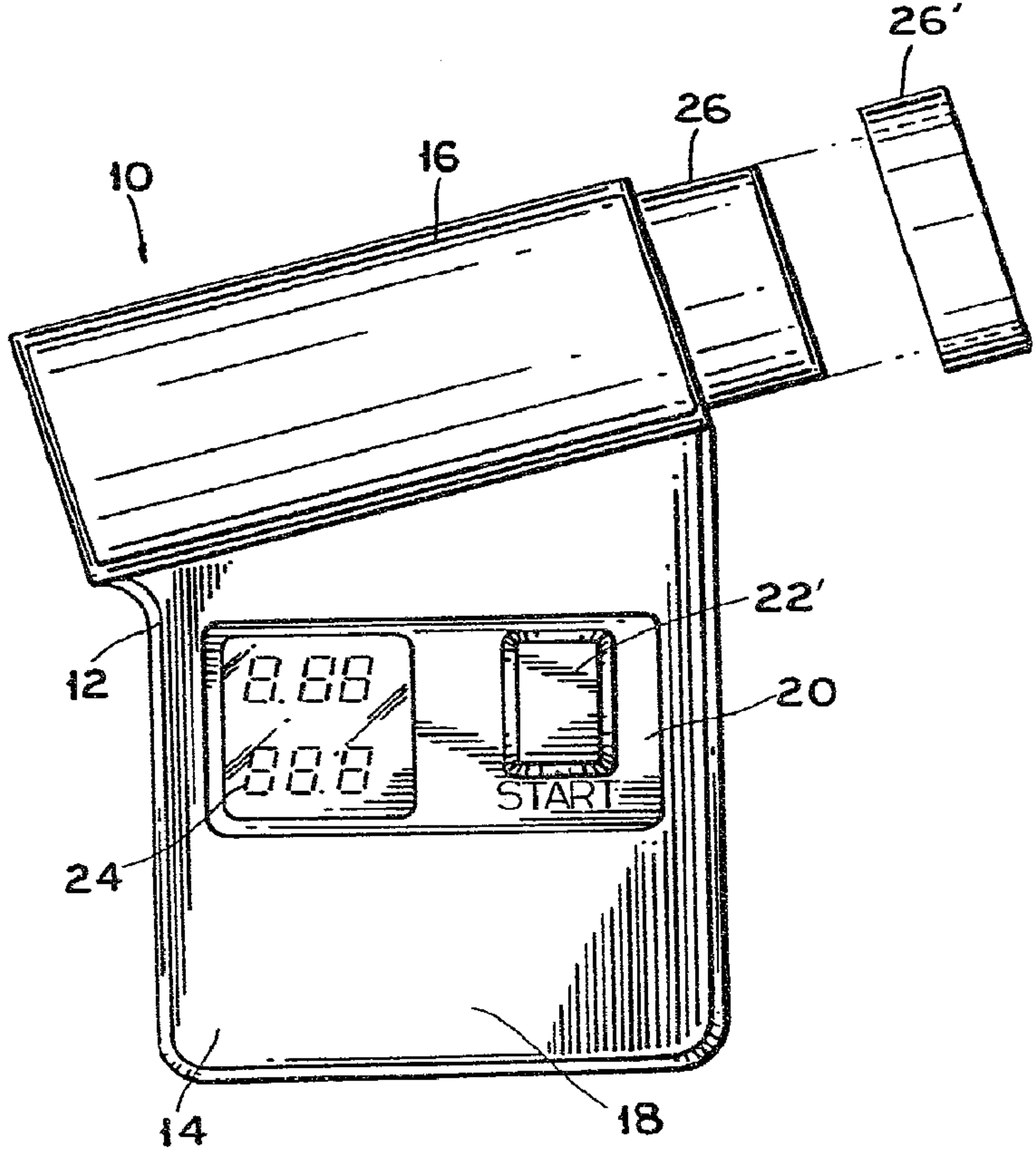

FROM INITIALIZATION S1
GET 4 VALUES FROM CH3
X1, X2, X3, X4
S21
RETURN
CALCULATE X̄. X̄ = (X1+X2+X3+X4)/4
S22
S23
CALCULATE VARIANCE (VAR)
THRESHOLD = 2×σ
VAR = [(X̄−X1)² + (X̄−X2)² + (X̄−X3)² + (X̄−X4)²] × 4/3
GET NEW VALUE FROM CH3
X5
S24
S25
X5<X̄?
YES
S26
X5 − X̄ > 2 VOLTS
YES
S28
GET VALUE FROM CH1 = X5′
S29
USE X5 = X5′×4
S27
(X5 − X̄) > X+ VAR
YES
TO FIG. 7C
S30
X1=X2 X2=X3 X3=X4 X4=X5
S39
15 SECONDS UP
YES
STOP
NO

FIG. 7B



FROM FIG. 7B
GET NEW VALUE FROM CH3: X6
S31
X6 > 128?
S32
YES
FLOW STARTED
S42
VOLUME = X5 + X6
S43
EXIT TO S3
$(X6-\bar{X}) > (X5-\bar{X})$?
S33
YES
S34
GET NEW VALUE FROM CH3: X7
S35
X7 > 128?
YES
FLOW STARTED
S40
VOLUME = X5 + X6 + X7
S41
X1 = X3
X2 = X4
X3 = X5
X4 = X6
S38
S36
$(X7-\bar{X}) > (X6-\bar{X})$?
YES
X1 = X4
X2 = X5
X3 = X6
X4 = X7
S37
15 SECONDS UP?
S39
YES
STOP
RETURN

FIG. 7C



10
16
26
26'
12
22'
20
24
14
18
START