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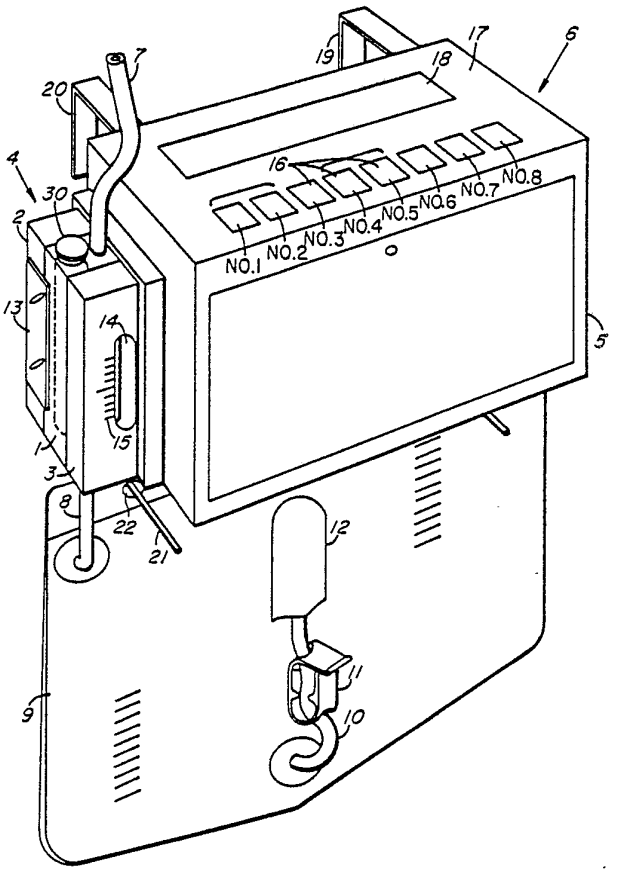
(54) Title: MONITOR FOR LIQUID LEVEL AND URINE FLOW

(57) Abstract

Optical liquid level sensor (28) comprising first and second prisms (38, 37) on opposite sides of a passage (39) where the liquid level is to be detected. Light is transmitted through the first prism (38) and in the absence of liquid the first prism (38) deflects light from the second prism (37). In the presence of liquid (50), the liquid refracts the light into the second prism (37) and down the axis of that prism in an uninterrupted path to a photodetector (47a) on that axis. Also disclosed is an apparatus including the level sensor (28) for measuring the volume of urine being produced by a patient over a predetermined period. The apparatus includes a measuring chamber (23) into which urine flows until the level sensor (28) is activated by the collection of a predetermined amount of urine. Then, valve (31) is opened to drain the chamber (23) and the number of times the valve is opened during a collection period is electronically counted as a measurement of the volume of urine produced by the patient during this collection period. The measuring chamber (23) and sensor (28) form a sterilizable, disposable unit (1).



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MONITOR FOR LIQUID LEVEL AND URINE FLOW

Cross-Reference to Related Application

This application is a continuation-in-part application of Serial No. 598,849, filed April 10, 1984, entitled Apparatus for Measuring the Flow of Urine from a Patient.

Background of the Invention

This invention is concerned with an optical, liquid level sensor and apparatus incorporating that sensor, particularly for measuring the flow of urine from a patient on a catheter.

There are many situations in which it is required to sense when a rising level of liquid reaches a certain point, such as to determine when a container is approaching the fill point or to drain a container which is being repeatedly filled. Because many liquids are substantially transparent, optical means can be used to determine when the liquid level is at a certain point. Such systems have the advantage of operation without interference with the liquid. One such liquid level sensing arrangement is disclosed in U.S. Patent No. 3,549,893, to Gibbs. The patent discloses an apparatus in which light is shone down a tube, across a container for liquid and then towards a photodetector which is in the shadow of a baffle in the light beam. The baffle casts a shadow on the detector and therefore renders it substantially inactive until liquid rises in the container to the level of the light beam. The liquid then refracts the light inwardly behind the baffle so as to activate the photodetector. The disadvantages with this arrangement are that some light leakage will occur to the photodetector during its inactive period, and this adversely affects the signal to noise performance of the equipment, and it is inconvenient to incorporate a baffle in a simple, compact design. Various other types of optical liquid level detectors are shown, for example, in U.S. Patent Nos. 3,384,885, 4,069,838 and 4,223,231.

In the medical field, it is often desirable to monitor liquid level in a container used in either the supply of liquid to, or the withdrawal of liquid from, a patient. In many situations, particularly when a patient is in a critical care unit, it is desirable to monitor accurately the amount of urine that the patient is expelling. The patient is on a catheter and the urine flows from the catheter into a device for measuring the flow and collecting the urine. Current devices are inaccurate or inconvenient to use. Many of these devices simply consist of a bag or cylinder with graduated markings on it that enables the attendant to periodically observe the level of urine collected. It is desirable that the urine output from a patient be monitored over a period of time and that the output rate be known. Automated recording of output data is an attractive means of achieving these ends which not only saves labor in the collection of the data, but also provides it in a form useful for the interpretation of the condition of the patient. U.S. Patent No. 4,343,316 to Jespersen discloses an automated urine collection and monitoring apparatus in which urine passes into a calibrated measuring chamber until the filling of the chamber is sensed by interruption of a light beam by the rising liquid level. At this point, the contents of the chamber are dumped into a collection bag and the volume dumped is electronically recorded. The number of volumes dumped is used to display digitally the total volume of urine collected and also the flow rate of urine per unit time. The apparatus in this patent must be connected to the main electrical supply and this severely restricts its portability and convenience. The measuring chamber in this patent is not an optimum design. Because the chamber empties relatively slowly, a valve upstream is closed to hold back the flow of urine. This blockage to the patient is undesirable and although the patent claims to have means to avoid blockage if the valve fails in the

closed position it is still very desirable to avoid such an arrangement. Further, the valve used is a pinch type and this suffers from the disadvantage of permanently crimping the tubing. This leads to relatively slow opening of the tube with the valve and the risk of tube fracture.

There is a need for a lightweight, relatively simply constructed, accurate liquid level sensor which can be used in the medical field. There is a need for such a sensor in a sterilizable, disposable module for a portable apparatus for monitoring the flow of urine from a patient which provides an accurate, visual numerical display of the amount of urine collected in a predetermined collection period and which uses a measuring chamber which empties rapidly and reliably.

Summary of the Invention

According to the invention there is provided a liquid level sensor apparatus for placement between a radiation source and a radiation detector, comprising first means for conducting radiation received from the source and second means for conducting radiation to the detector, the first means being for alignment with the sensor on a first axis and the second means for alignment with the detector on a second axis, the first and second means being spaced apart to form a liquid level sensing zone between them such that, when the sensor is in place between the source and detector and the liquid level has not reached the zone, the radiation conducted by the first means is directed away from the second means to render said detector inactive, and in the presence of liquid in the zone the radiation from the first means is refracted by the liquid to the second means to be conducted thereby along the second axis to the detector to activate the detector. Preferably, the first and second axes form a common optical axis.

The invention also provides for measuring the flow of urine from a patient by repeatedly collecting in said apparatus, and removing from said apparatus, a predetermined volume of urine. The apparatus comprises a measuring chamber for collecting said volume of urine; an inlet to said chamber for connection to a patient; an outlet from said chamber for said removal of said urine; means for intermittently interrupting the flow of urine from said outlet so as to allow said volume of urine collected in or removed from said module; a plenum chamber in communication with said measuring chamber for promoting said removal of said urine; and means for sensing when said volume of urine has been collected, comprising means for accepting radiation into said apparatus and means for emitting said radiation from said apparatus in a predetermined path for detection, said sensing means causing said radiation to be deflected from that path until said volume of urine has been collected. The accepting means comprises first radiation transmissive means on a first axis and said emitting means comprises second radiation transmissive means on a second axis, said first and second means being spaced apart to form a urine level sensing zone between them. Preferably said first and second axis are a common axis.

Preferably the first means has a face at the interface with the sensing zone in the above embodiments which is inclined in a plane at an acute angle to the first axis so that the radiation from the first means is refracted at that interface away from the second means. Preferably, the second means has a face at the interface between said zone and the second means lying in a plane substantially parallel to the face of the first means.

Preferably, each of the first and second means comprises a solid, substantially cylindrical rod made of a material substantially transparent to the radiation, such as a clear plastic material.

The invention also provides a lightweight, portable apparatus incorporating this level sensor for monitoring the flow of urine from a patient on a catheter which provides an accurate measurement, is battery operated, and includes a display of urine flow volume data which enables the attendant to chart accurately the urine output of the patient over a prolonged period of time, for example, 24 hours. The data over this 24 hour period is stored in the memory of the apparatus and can be retrieved and visually displayed at the command of the attendant.

This apparatus comprises a measuring chamber having a predetermined volume, for example, 10 milliliters. This chamber is adapted to be connected to the catheter, and has a valve near its lower end that moves between a closed position, at which urine is collected within the chamber and, an open position, at which the urine flows from the chamber into a collection bag. The level sensing device of the invention is located near the upper end of the chamber and it senses when the urine level in the chamber reaches the level sensing device, and then provides an electronic signal indicating that this condition is present. Mechanical means are connected to the valve and they are driven by an electrical actuator which responds to the electronic signal to open the valve. The urine in the chamber thus flows from the chamber and into the collection bag or the like.

This combination of chamber, valve means, and sensing device provides a way of measuring the amount of urine being expelled by the patient. Every time the patient excretes a preselected quantity of urine, for example, 10 milliliters, it is collected in the chamber. The 10 milliliters of urine fills the chamber with the urine until the urine level is opposite the sensing means, which then responds to open the valve and drain the urine from the chamber. Therefore, the electronic signal not only serves to open the valve, but also is an accurate

indication that exactly 10 milliliters of urine has been expelled by the patient. Thus, for example, if the valve is opened three times in a pre-selected collection period, for example, an hour, this corresponds to a urine output of 30 milliliters of urine per hour.

Recording means record the number of times the chamber is filled in the pre-selected collection period. This recording means visually displays the volume data on, for example, a dot matrix display readily observable by an attendant. This panel may optionally be illuminated. The recording means is designed so that over a given period of time, for example, 24 hours, the volume data is stored in the memory circuitry of the apparatus as a series of numbers corresponding to the different amounts of urine collected during each collection period of a series of sequential collection periods occurring during the 24 hour period. For example, during the first three hours the patient may have expelled 50 milliliters of urine during each hour and then stopped urinating so that the reading is zero during the fourth hour. The apparatus is designed so that for each hour interval the attendant could scan the memory and obtain a reading of the amount of urine expelled for each hour over the 24 hour period, thus being able to chart the urine production during each hour over the twenty-four hour period. The apparatus is also designed so that during any given hour of time the attendant may obtain on command an instantaneous reading of the urine production for that portion of an hour time interval.

Another important feature of this invention is that the apparatus is powered by conventional batteries. This makes it highly convenient for the apparatus to be used in a hospital, avoiding the necessity of plugging the apparatus into a source of alternating current. This is not only more convenient, but is also safer. In order to minimize the drainage of power from the batteries, the

apparatus is adapted to operate between a high power mode and a low power mode. During the high power mode, the apparatus is enabled to carry out all its functions. During the low power mode only a limited number of functions are operable. The apparatus cycles automatically between the high and low power modes.

Brief Description of the Drawings

Some preferred embodiments of the invention are illustrated in and by the following drawings in which like reference numerals indicate like parts and in which:

FIGURE 1 is a perspective view of an apparatus of this invention, showing a liquid flow measuring module in place on a control unit and connected to a liquid collection bag;

FIGURE 2 is a cross-sectional view of the measuring module;

FIGURE 3 is a rear view of the whole of a measuring module of the type shown in Figure 2, taken in the direction of arrow 3 in Figure 2;

FIGURE 4 is a top view of the whole of a module of the type shown in Figure 2, taken in the direction of arrows 4 in Figure 2;

FIGURE 5 is a bottom view of the whole of a module of the type shown in Figure 2, taken in the direction of arrows 5 in Figure 2;

FIGURE 6 is a cross-sectional view, partly broken away, of a module of the type shown in Figure 2 in place on the control unit, as shown in Figure 1, and showing the liquid level sensor of the invention;

FIGURE 7 is a schematic illustration showing the operation of the liquid level sensor of Figure 6 in the absence of liquid;

FIGURE 8 is a schematic illustration showing the operation of the liquid level sensor of Figure 6 in the presence of liquid;

FIGURE 9 is a schematic illustration of an alternative liquid level sensor of the invention, showing its operation in the absence of liquid;

FIGURE 10 is a schematic illustration of the operation of another liquid level sensor according to this invention, showing its operation in the absence of liquid;

FIGURE 11 is a plan view of the top of the control unit showing the control panel and display screen where data related to the flow of liquid can be displayed;

FIGURE 12 is a list of messages which can be displayed on the display screen shown on the panel in Figure 11;

FIGURE 13 is a schematic drawing showing the control circuitry in the central unit;

FIGURES 14A and 14B are flow charts illustrating the sequential operation of the control unit in the apparatus of this invention.

Detailed Description of the Drawings

Referring to Figure 1, there is shown an apparatus according to the invention for monitoring the flow of urine from a patient on a catheter. The apparatus comprises a removable liquid measuring module 1 which incorporates the liquid level sensing system of the invention, as will be explained in more detail below.

Measuring module 1 is sandwiched between two plates 2 and 3 to form a liquid monitoring unit 4 attached to the side of the housing 5 of an electronic control unit 6. Measuring module 1 is provided with an inlet tube 7 for connection to a catheter (not shown) and an outlet tube 8 connected to a collection bag 9. Bag 9 is fitted with a drain tube 10 upon which is mounted a tube clamp 11 which normally keeps drain tube 10 closed. The end of tube 10 is normally stored in a pocket 12 on the face of bag 9 until it is desired to empty the bag 9.

Measuring module 1 is kept in place between plates 2 and 3 by a gate 13 slidably mounted on one plate 2 so that it can either slide over module 1 to prevent it from

falling out from between the plates or be withdrawn over plate 2 to allow module 1 to be removed. Each plate has a window 14 through it (one of which is shown in Figure 1) so that an attendant can observe the contents of the measuring module 1. A scale 15 alongside window 14 provides an approximate indication of the volume of urine in module 1.

Control unit 6 is provided with a number of keys 16 on its top surface 17 to operate control unit 6 and electronically monitor the flow of urine from the patient. Data relating to the flow of urine and condition of the equipment are displayed in panel 18, which is conveniently located on the top 17 of control unit 6. Batteries (not shown) for providing power to the electric circuitry are contained within housing 5. The operation of the control unit 6 will be described in further detail below.

Control unit 6 may conveniently be provided with hooks 19 and 20 on its rear face to attach the apparatus to a patient's bed. Additional hooks underneath control unit 6, one of which is shown at 21 in Figure 1, are used to carry collection bag 9 by engagement through holes through the top of the bag, one of which is shown at 22 in Figure 1.

Turning to Figure 2, there is shown a side cross-sectional view of measuring module 1 of this invention. Module 1 comprises a measuring chamber 23 having a predetermined volume such as 5 or 10 ml. Preferably chamber 23 has a volume of 10 ml. Measuring chamber 23 has at its upper end an inlet passage 24 for connection to inlet tube 7 as shown in Figure 1. Chamber 23 has at its lower end an outlet passage 25 which is in communication with a drain port 26 for attachment to outlet tube 8 as shown in Figure 1. Another passage 27 leads from the upper end of chamber 23 past a liquid level sensing device 28 into an overflow chamber 29 whose lower end is also in

communication with outlet port 26. Overflow chamber 29 is vented to the atmosphere by means of a hydrophobic bacterial filter 30 at its upper end. A valve 31 is located at the bottom of measuring chamber 23 for closing outlet 25 from chamber 23. As can be seen in Figure 2, outlet 25 sweeps in a continuous, gradual bend 32 from the bottom of measuring chamber 23 into a generally cylindrical valve compartment 33 which is in communication through port 34 to the outlet 26. The valve 31 comprises a flexible, circular diaphragm 35 between the walls of valve compartment 32. Diaphragm 35 can be deformed by pressure from a piston (not shown) from the open position shown in Figure 2 to flex and bear against outlet 25 to seal that outlet and allow measuring chamber 23 to be filled. To achieve a more positive closure, diaphragm 35 is provided with a raised central portion 35a which will plug outlet 25 when the valve is closed. Diaphragm 35 is preferably made of a rubbery material which flexes in response to pressure from the piston and yet will rapidly withdraw without deformation from outlet 25 when the piston is withdrawn. It has been found that natural rubber has the desired characteristics for diaphragm 35.

In operation, urine from the patient enters measuring chamber 23 via inlet 24 and, with valve 31 closed, begins to collect in chamber 23 until that chamber is filled and the rising liquid level enters passage 27 to activate the liquid level sensor 28. The sensor 28 then generates an electronic signal which causes valve 31 to open and rapidly dump the contents of measuring chamber 23 through outlet 25 and port 34 to the main outlet 26 and into the collection bag 9, as shown in Figure 1. The smooth gradual bend 32 in outlet 25 from measuring chamber 23 contributes to sweep out any solid material and also to rapidly and completely empty measuring chamber 23. When a predetermined time passes which is sufficient to allow chamber 23 to empty, valve 31 is closed again to allow

chamber 23 to refill. Overflow chamber 29 acts as a plenum chamber to encourage rapid emptying of measuring chamber 23 and therefore more accurate measurement since the chamber will be emptied quickly enough before a significant further amount of urine enters it. Overflow chamber 29 also acts to conduct excess urine through outlet 26 to collection bag 9 in the unlikely event that valve 31 fails in the closed position and does not open. Under these circumstances, measuring chamber 23 will fill and excess urine will flow through passage 27 to spill over into overflow chamber 29. Preferably, there is no valve in the apparatus upstream of measuring chamber 23, thus ensuring that there will always be an unrestricted passage between the patient and the collection bag 9. If overflow chamber 29 is used and it becomes full of urine, the hydrophobic nature of filter 30 will prevent the outward flow of urine through the filter.

Figure 3 shows the rear of measuring module 1. A locating rib 36 on an exterior side wall of module 1 is for engagement with a corresponding channel (not shown) in the face of plate 3 shown in Figure 1 to orient the module 1 for correct alignment between plates 2 and 3, as shown in Figure 1. Figure 3 also illustrates a preferred construction of the liquid level sensing device 28 of the invention which comprises two prism elements 37 and 38 disposed opposite each other across channel 27 with gap 39 between them. Prism elements 37 and 38 are made of a light- transmissive material and can conveniently be fabricated from a clear plastic material such as polystyrene, polycarbonate or an acrylic plastic. Preferably, with the exception of diaphragm 35, module 1 is entirely made from such a material, typically in two halves by injection molding which are then glued together to form module 1. Such a construction allows the module 1 to be made inexpensively and therefore it can be disposed of after use. This has the advantage of making the unit

relatively inexpensive and avoiding contamination. Indeed, module 1 with its inlet and outlet tubes 7 and 8, respectively, and the collection bag 9 can be sold as a single, disposable, sterilizable unit which provides a greater convenience in the operation of the equipment of this invention.

The liquid level sensing system 28 of this invention is shown in greater detail in Figure 6 which shows, in partial cross-section, the level sensing system 28 in memory module 1 when in place between plates 2 and 3. Prism element 38 is a solid, radiation transmissive, substantially cylindrical shaped body in axial alignment with a source of radiation 40a located in a chamber 40 inside plate 2. The source of radiation is preferably a light-emitting diode which emits a beam of infrared light through a collimating channel 41 in plate 2 along the axis of that channel to impinge upon an input face 42 of prism element 38 which lies in a plane substantially perpendicular to the axis. The light then travels down element 38 to an output face 43 which lies in a plane at an acute angle α to the axis of that element, as is shown in Figure 7. Across the gap 39 in channel 27 between elements 38 and 37 is an input face 44 of element 37. Input face 44 is for receiving light from element 38 and transmitting it down element 37 to exit face 45 of prism element 37 which lies in a plane substantially perpendicular to an axis in alignment with a collimating channel 46 in plate 3 which leads to a chamber 47 in that plate containing a photodetector 47a. Usually, the light-emitting diode, elements 38 and 37 and the photodetector will be aligned along a common optical axis shown by the broken line XX in Figure 6. To improve optical transmission and minimize entry of stray light into elements 37 and 38, the external ends of these elements 42 and 45, respectively, at the outer walls of module 1 are preferably surrounded by annular air spaces 48 and 49,

respectively, around the terminal portions of elements 37 and 38 at ends 42 and 45 and cut into the body of module 1. These annular areas exposed to the air and ends 42 and 45 are polished to an optical finish for that improvement. Elements 37 and 38 can either be inserts into the body of measuring module 1 or, more preferably, can be formed integral therewith.

The operation of level detector 28 can be understood more readily by reference to Figures 7 to 10. Figure 7 shows the passage of a light beam A through element 38 and into space 39 in channel 27 when liquid has not risen into that space. Under these circumstances, the light beam is refracted at output face 43 of element 38 at the interface between the body of that element and the air gap so as be directed away from receiving element 37 in the direction of arrow A. This refraction occurs due to the difference in the refractive index between air and prism element 38. Consequently, the light beam does not reach the photodetector which remains inactive. Referring to Figure 8, when liquid 50 rises into the space 39 between elements 37 and 38 the light beam remains substantially unrefracted at the interface of the liquid 50 and element 38, and thus impinges upon element 37, to pass along it in the direction of arrow B to be received by the photodetector 46a. This occurs because the refractive indices of the urine and prism element 38 are substantially equal. This activates the photodetector to indicate that the predetermined volume of liquid has been collected by the measuring chamber. Preferably, the receiving face 44 of element 37 is parallel to that of element 38 as shown in Figures 7 and 8. However, the receiving face 44 can be substantially perpendicular to the axis of that element as shown in Figure 9. In a similar manner to Figure 7, when there is no liquid between the prisms 37 and 38 the light beam from first prism 38 in Figure 9 will be refracted away from second prism 37, as shown by arrow C. A further

alternative construction is shown in Figure 10, where elements 37 and 38 have conical faces 51 and 52 across space 39. Under these circumstances, elements 37 and 38 are preferably slightly axially offset since deposits can form on the tips of the cones which tend to transmit light directly from transmitting element 38 to transmitting element 37 even when there is no body of liquid between the two elements. Again, Figure 10 shows the light beam D being refracted away from second prism element 37.

As is shown in Figure 7, the output face 43 of first prism element 38 lies in a plane at an acute angle α to the axis of that element. It has been found that if this angle is less than about 30° light tends to leak from the prism to pass into the other prism element 37 and also tends to allow wetting of face 43 which can make that face act as a lens to conduct light to the other prism element. On the other hand, if angle α is much more than about 60°, the separation required between the two prism elements becomes so large that the accuracy sensing device deteriorates. Therefore, angle α is preferably from about 35° to about 60°, more preferably from about 45° to about 50° and most preferably about 50° since this angle represents the best compromise of low leakage versus minimum separation.

The preferred keyboard arrangement for the control unit in the apparatus of this invention is shown in Figure 11. Eight keys are shown but, of course, a different number with different functions could be used as will be apparent to one skilled in the art.

Preferably, the software in the apparatus is constructed so that data useful to the attendant and display messages which are to be amended can be scanned in a cyclic manner using the read data keys nos. 1 and 2 (Figures 1 and 11). These keys access messages nos. 8, 9 and 10, listed in Figure 12 which respectively relate to the current collection period, the amount collected in

that period and the time and date; a showing of the low volume alarm set; and the total collected for the last number of hours set in the equipment.

As can be seen in Figure 12, the possible display includes a number of warning messages nos. 1 to 7 and 12 to 14. No-1 warns that no measuring module is in place, no. 2 that the measuring chamber is being emptied, no. 3 that the measuring chamber is not emptying properly, no. 4 that there is an electrical problem in the system, no. 5 that the equipment is conducting a self-test, no. 6 that the volume collected in the last collection period is less than that set as a minimum in the equipment, no. 7 that the collection bag is full, no. 12 is the first message displayed when the equipment is turned on, which calls for the attendant to set the time and date, no. 13 indicates that the batteries are running low, and no. 14 is indication that the self-testing has been selected. This self-testing can only be conducted by a technician manipulating the internal circuit of the apparatus.

Key no. 3, shown in Figure 11, moves a cursor (not shown) along under the message displayed in panel 18 to the point where it is desired to adjust the message. The message is then adjusted to increase numerically using key no. 4 or to decrease using adjustment key no. 5. In this manner the alarm levels, time, and date, etc. can be adjusted. Key no. 6, shown in Figure 11 cancels the alarms. Key no. 7 illuminates panel 18 and key no. 8 is a general cancel key.

Referring to Figure 13, there is shown the schematic control circuitry 53 for the control unit 6. The central processing unit CPU 54 of the circuitry 53 controls the functions of the apparatus. This is a conventional microprocessor sold by OKI-Data, Item No. 80C39. This is a CMOS microprocessor with an EPROM memory. This microprocessor is connected through a data bus to the display panel 18, which has on its underside an

electroluminescent light 55 which may be turned on at the command of the attendant. Panel 18 can be a liquid crystal display or, more preferably to accommodate more characters, a dot matrix display. The apparatus 6 has associated with it an operating keyboard 516, including keys No. 1, No. 2, No. 3, No. 4, No. 5, No. 6, No. 7 and No. 8 (as shown in Figure 11). The attendant provides various command inputs to the CPU 54 by depressing one or more of the keys. This will be discussed in greater detail in connection with the flow chart shown in Figures 14A and 14B. A real time clock 56 is connected to the CPU 54 and it functions to cycle the control circuitry 53 between a low power and high power mode of operation.

The control circuitry 53 is provided with an alarm system for providing both an audio and visual alarm when the rate of urine flow is too low, the collection bag is full, or both. This alarm system includes an electronic switch 57 and a light 58 which is carried on the housing 5 at a position that is readily observable by the attendant. A buzzer enable switch 59 permits the attendant to disable the buzzer 60 if desired.

The CPU 54 is driven by four standard D size alkaline batteries 61. Theses batteries 61 are connected to the CPU 54 through a control switch 62 and voltage regulator 63 to adjust the voltage so that it is constant. There is also provided a low battery detect circuit 64 which will give a signal to the CPU 54 when the batteries need to be replaced. The CPU 54 is electronically coupled to the optical sensor 28 and has an output coupled to the actuator circuitry 65 for the actuator 66 which operates the valve 31. Any suitable mechanical device will serve as an activator for the valve 31. The CPU 54 is programmed to open and close the valve 31 in response to the signal from the optical sensor 28.

The CPU 54 is programmed in accordance with conventional practices. A programmer, by following the

flow charts set forth in Figures 14A and 14B, will be able to program the OKI-Data processor to provide the control functions indicated by the flow diagrams. It will be appreciated however, that one skilled in the art can devise different software to achieve the desired results for the equipment of this invention.

OPERATION

The operation of the apparatus of this invention will now be discussed in connection with the flow diagrams shown in Figures 14A and 14B, the control circuitry 53 shown in Figure 13, the control panel shown in Figure 11 and the panel messages shown in Figure 12. The attendant initially turns on the power by closing switch 62. Message No. 12 (Figure 12) appears on the display panel and he next sets the clock 56 if the clock is not correctly telling the time of day. This is accomplished by depressing key No. 3 for adjustment to move a cursor to the part of the message to be changed and depressing either key No. 4 or key No. 5 to increase or decrease the numbers displayed. By setting the time, all stored urine output data is erased from the memory of the CPU 54.

The valve 31 is initially in the closed position as shown in Figure 2, thus enabling the measuring chamber 23 to fill with urine. Typically, most patients will expel urine at a rate in excess of 40 milliliters per hour. If the patient does not urinate at this rate, a dangerous condition exists and the buzzer alarm 60 is actuated, indicating to the attendant that this dangerous condition exists. This alarm rate can be changed to another level, if desired by calling up the level message No. 9 using read data keys Nos. 1 or 2 and then changing the valve using the select key No. 3 and adjust keys Nos. 4 and 5.

Whenever it is in the high power mode, the CPU 54 checks the inputs from the optical sensor 28 to determine if the level of urine has reached the sensor. If it has not, indicating that the chamber is not full, it then

checks to see if the collection period has ended. In this case the collection period has been set for one hour. If the hour has not changed, going from the first to the second collection period in a series of, for example, 24 hours, the CPU 54 then checks to see if any of the keys have been depressed. If they have, then the function of the depressed key or keys will be performed. Assuming none of these keys have been depressed by the attendant, the CPU 54 then automatically switches to the idle mode.

Assume that when the CPU 54 comes out of the idle mode it detects that the chamber 23 is full. When this event occurs, the CPU 54 then activates the valve actuator 66 and opens the valve 31. It automatically then closes the valve 31 after a sufficient time is passed to permit the chamber 23 to drain the ten milliliters of urine collected. At this point, the CPU 54 then adds 10 milliliters to the count of urine collected for the collection period in question. In other words, if the first ten milliliters were collected during this hour, the number ten (10) is added to the memory of the CPU 54, indicating that the first ten milliliters had been collected. This is the first 10 milliliters for that hour and no urine output data has been previously stored in the memory for this first hour. If it was the third reading in the hour, the data stored in the memory would indicate that 30 milliliters had been collected for the hour. This process of monitoring the level of urine in the chamber 23, emptying the chamber 23 when ten milliliters has been collected, and then adding ten milliliters to the memory of the CPU 54, is continued throughout the course of the collection period, in this case, one hour. This collection process is continuous.

The CPU 54 is programmed (1) to count the number of times the chamber is filled with 10 milliliters of urine during the one hour collection period, (2) to store this number in the memory, and (3) then, during the next hour,

repeat this operation storing the number of times the chamber is filled in separate storage in the memory for the next hour in the series of 24 hour collection periods. This is accomplished by the CPU 54 being programmed to check to determine if the hour has changed. If the hour has changed, the measurement corresponding to the volume of urine is then placed in a separate storage register which may be accessed at any time during the 24 hour cycle by the attendant. This is accomplished by simply depressing the No. 1 or 2 keys to cycle the available messages on the display screen until the desired message is displayed.

At the end of each hour, the program checks to determine if during that hour less than 40 milliliters of urine was produced, or whatever minimum has been entered. If the urine production is less than that minimum per hour, then the CPU 54 will display a low volume message No. 6 (Figure 12) and actuate the audio and visual alarm indicating to the operator that a dangerous condition exists. In addition to checking for the rate of urine production, the CPU 54 is also programmed to check the level of urine in the bag. For example, if the bag being used is capable of holding 1800 milliliters of urine, the CPU 54 is programmed to check when 1800 milliliters of urine has been collected, indicating the bag is full. If this is the case, then the bag full indicator is actuated to sound the buzzer 60 alarm and the bag full message No. 7 will be displayed. Pressing the No. 6 key on the panel will cancel the low volume or the bag full alarm. In many instances it will be desirable to illuminate the display panel 18. This is accomplished by actuating a switch by depressing the No. 7 key.

WHAT IS CLAIMED IS:

1. An apparatus for measuring the flow of urine from a patient by repeatedly collecting in said apparatus, and removing from said apparatus a predetermined volume of urine, said apparatus comprising:

a measuring chamber for collecting said volume of urine;

an inlet to said chamber for connection to a patient;

an outlet from said chamber for said removal of said urine;

means for intermittently interrupting the flow of urine from said outlet so as to allow said volume of urine to be collected in or removed from said chamber; and

means for sensing when said volume of urine has been collected, comprising means for accepting radiation into said apparatus and means for emitting said radiation from said apparatus in a predetermined path for detection, said sensing means causing said radiation to be deflected from that path until said volume of urine has been collected.

2. A liquid level sensor apparatus for placement between a radiation source and a radiation detector, said sensor comprising:

first means for conducting radiation received from said source;

second means for conducting radiation to said detector;

said first means being for alignment with said source on a first axis and said second means being for alignment with said detector on a second axis;

said first and second means being spaced apart to form a liquid level sensing zone between them such that, when said sensor is in place between said source and said detector, in the absence of liquid in said

zone the radiation conducted by said first means is directed away from said second means to render said detector substantially inactive, and in the presence of liquid in said zone said radiation from said first means is not directed away from said second means so as to be conducted by said second means along said second axis to said detector to activate said detector.

3. An apparatus as claimed in Claim 1, wherein said accepting means comprises first radiation transmissive means on a first axis and said emitting means comprises second radiation transmissive means on a second axis, said first and second means being spaced apart to form a urine level sensing zone between them.

4. An apparatus as claimed in Claim 1, further comprising a plenum chamber, in communication with said measuring chamber for promoting said removal of said urine.

5. An apparatus as claimed in Claim 1, wherein said sensing means comprises two prisms.

6. An apparatus as claimed in Claim 2 or 3 wherein said sensing means are such that when said apparatus is in place between said source and detector substantially all the radiation from said source passes through said apparatus to said detector.

7. An apparatus as claimed in Claim 2 or 3, wherein said first means has a face at the interface with said sensing zone which is inclined in a plane at an acute angle to said first axis.

8. An apparatus as claimed in Claim 7, wherein said angle is from 35° to 60°.

9. An apparatus as claimed in Claim 8, wherein said angle is from 45° to 50°.

10. An apparatus as claimed in Claim 7, wherein said second means has a face at the interface between said zone

and said second means lying in a plane substantially parallel to the said face of said first means.

11. An apparatus as claimed in Claim 2 wherein each of said first and second means comprises a solid, substantially cylindrical rod made of a material substantially transparent to said radiation.

12. An apparatus as claimed in Claim 3, wherein each of said first and second means comprises a solid, substantially cylindrical rod.

13. An apparatus as claimed in Claim 11 or 12, wherein first means has an input face for receiving said radiation from a radiation source and said second means has an output face for transmitting said radiation for detection, said faces lying in planes substantially parallel to one another and substantially perpendicular to the respective longitudinal axes of said first and second means.

14. An apparatus as claimed in Claim 13, wherein said first and second means are embedded in a solid body of material and said input and output faces and a portion of each of said cylindrical rods around the circumference thereof adjacent said faces form surfaces exposed from said body of material, said surfaces being optically polished to improve transmission of the radiation.

15. An apparatus as claimed in Claim 2 incorporated in a disposable apparatus for measuring urine flow, said disposable apparatus comprising a measuring chamber having a predetermined volume and having an inlet passage for connection to a patient on a catheter and an outlet passage, said outlet passage having a valve movable from a closed position, to allow said chamber to be filled to said predetermined volume, and an open position, to allow said chamber to be emptied.

16. An apparatus as claimed in Claim 1 or 15, further comprising means for recording the volume of urine collected by said measuring chamber during a predetermined

collection period and for visually displaying these volume data.

17. An apparatus as claimed in Claim 16, wherein the recording means counts the number of times said measuring chamber is filled with urine during a collection period and converts this reading into a number equal to the volume data to be displayed.

18. An apparatus as claimed in Claim 17, wherein the recording means includes memory means which retrievably stores the volume data over a given period of time as a series of numbers corresponding to the different amounts of urine collected during each individual period of the series of sequential collection periods.

19. An apparatus as claimed in Claim 16, including means which provides a visual display of the instantaneous amount of urine collected during the collection period in which the measurement is being made.

20. An apparatus as claimed in Claim 16, including means for collecting and storing the urine from the measuring chamber.

21. An apparatus as claimed in Claim 20, wherein the recording means provides an alarm when the collecting and storage means is full.

22. An apparatus as claimed in Claim 16, including means for providing an alarm when urine is not collected at a predetermined rate.

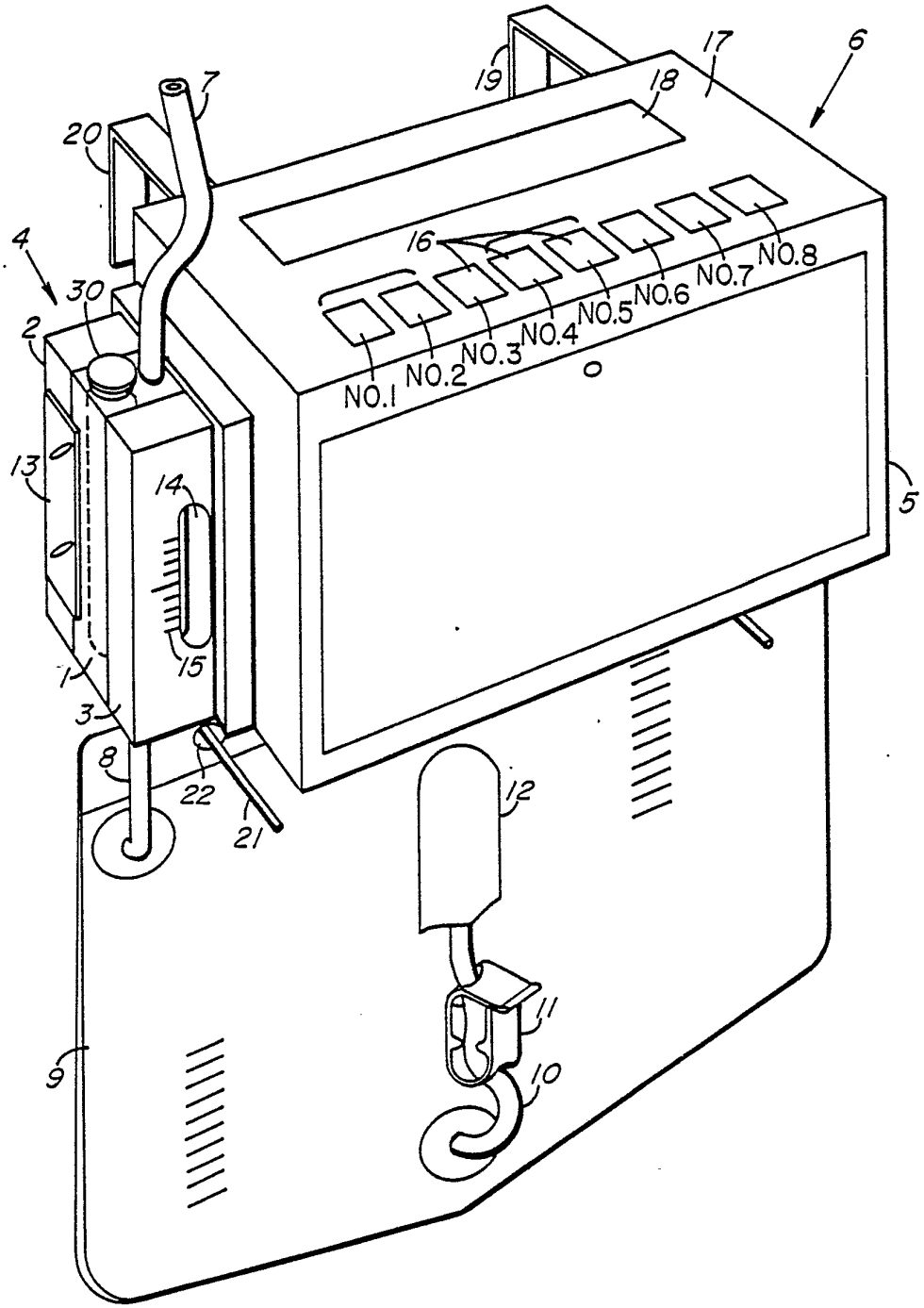

FIG. 1

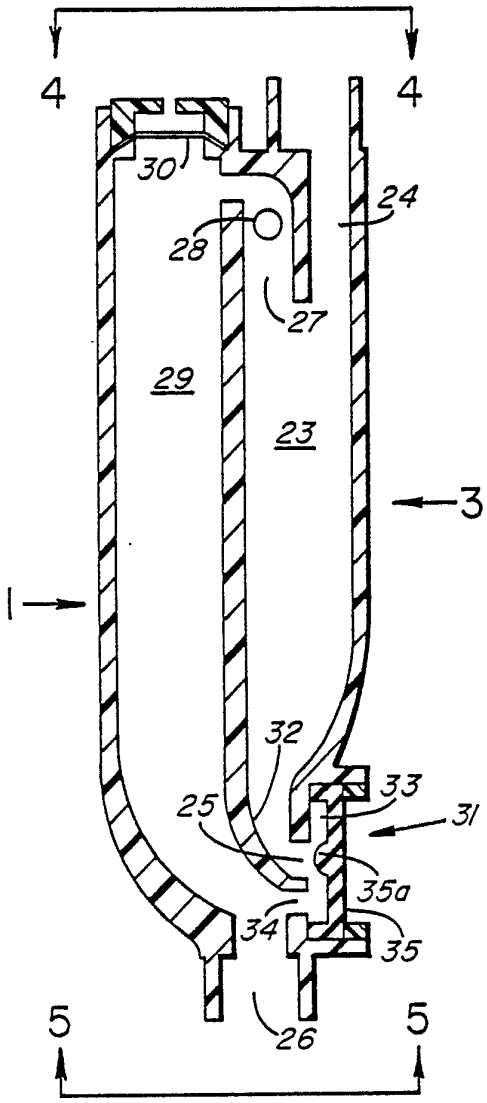

FIG. 2

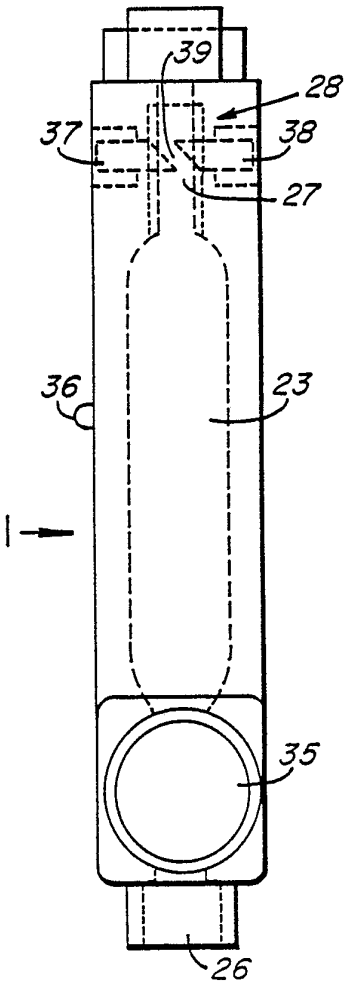

FIG. 3

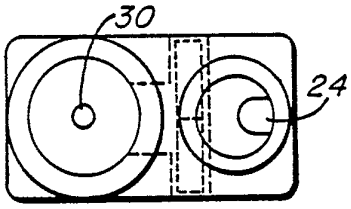

FIG. 4

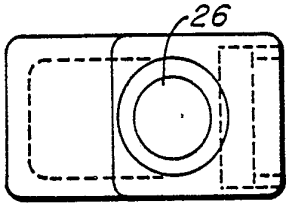

FIG. 5

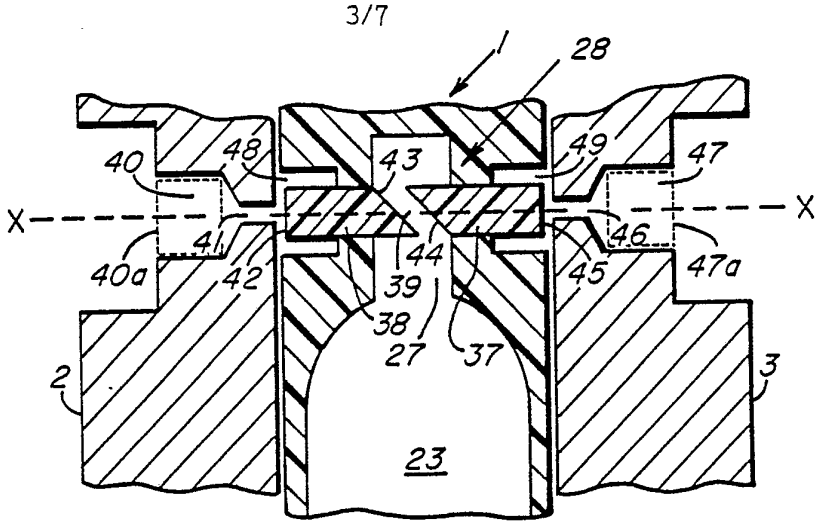

FIG. 6

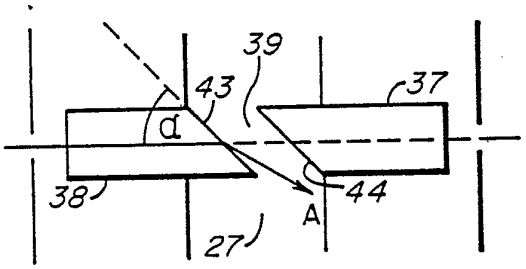

FIG. 7

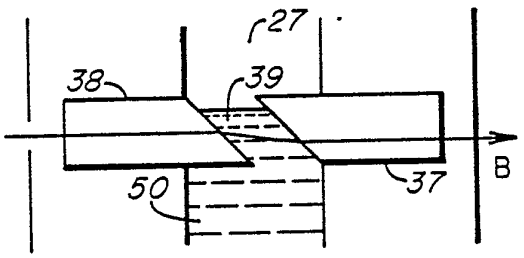

FIG. 8

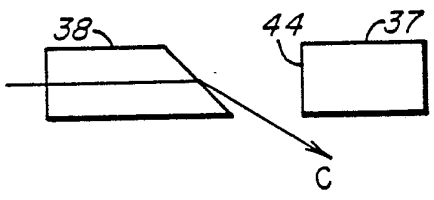

FIG. 9

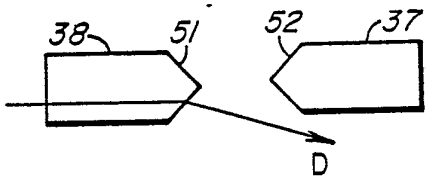

FIG. 10

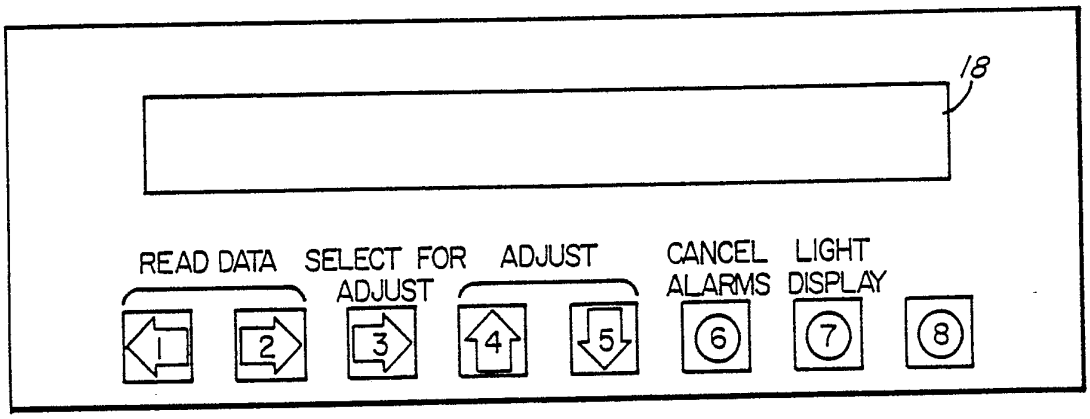

FIG. 11

1. STANDBY/NO DISPOSABLE/10:35/08/05/85
2. PLEASE WAIT, SYSTEM DRAINING
3. WARNING: SYSTEM IS NOT DRAINING, CHK. DISP.
4. SYSTEM PROBLEM-FAULT #1-15 — PLS. FIX!
5. SELF TEST IN PROGRESS — PLEASE WAIT
6. TOTAL VOLUME LAST HR LESS THAN 40 ML.
7. BAG FULL — PLS EMPTY & PRESS #6
8. 10:00AM TO 10:35 = 70 ML/10:35/08/05/85
9. LOW VOLUME ALARM LEVEL = 40 ML/HR
10. TOTAL FOR LAST 12 HRS = 1200 ML
11. 7AM TO 8AM = 130 ML/8AM TO 9AM = 110 ML
    (LAST 24 HOURS ARE CONCATENATED AS SHOWN ABOVE. DISPLAY "NO DATA" FOR ANY HOUR THAT UNIT WAS NOT RUNNING WITH CARTRIDGE INSERTED).
12. PLEASE SET TIME/DATA XX00:00/01/01/85
13. BATTERY LOW/PLS CHANGE/RECORD DATA FIRST
14. CONTINUOUS SELF TEST SELECTED/SYSTEM OK

FIG. 12

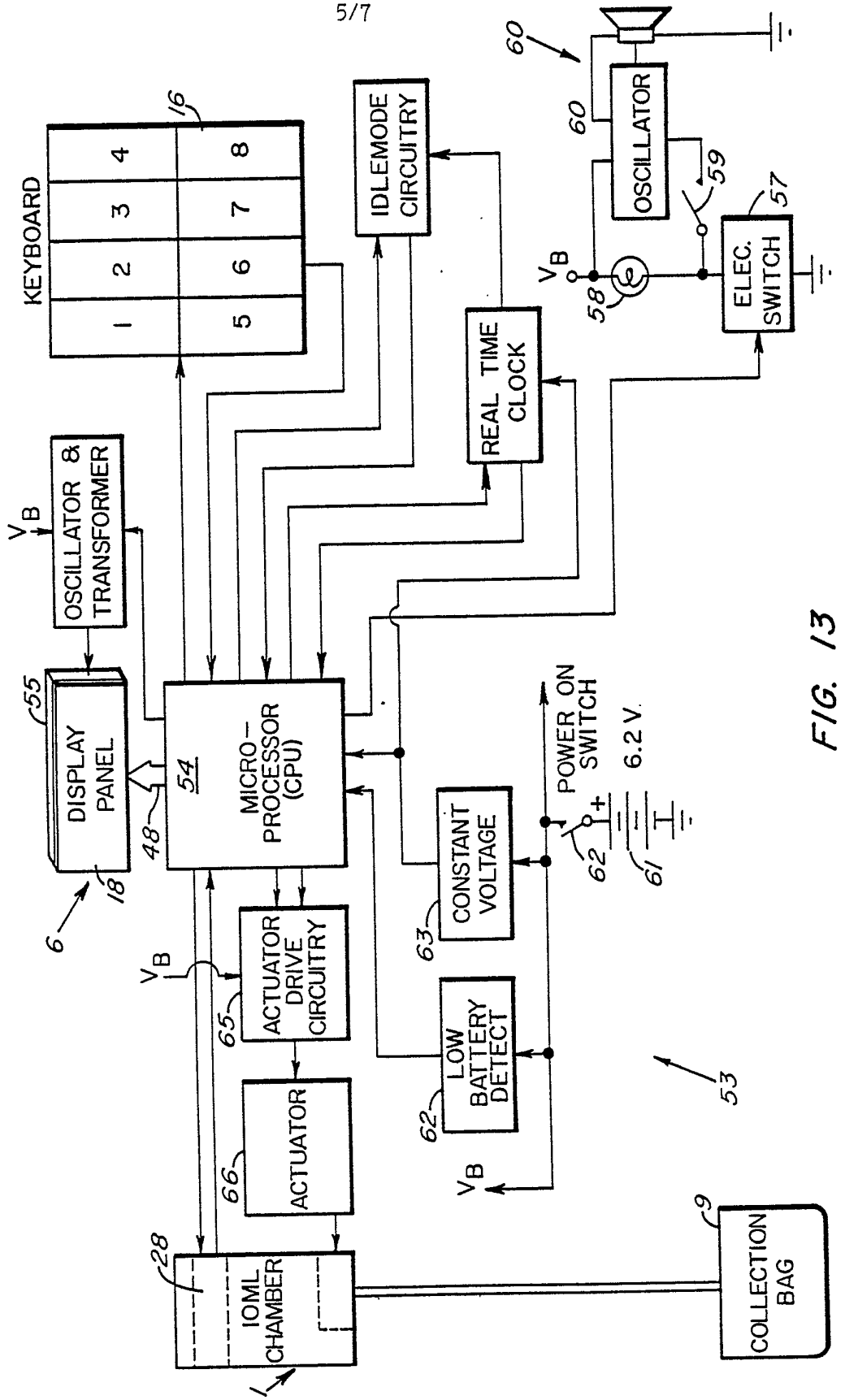
KEYBOARD
1
2
3
4
5
6
7
8
16
IDLEMODE CIRCUITRY
60
OSCILLATOR
59
57
ELEC. SWITCH
58
V_B
REAL TIME CLOCK
OSCILLATOR & TRANSFORMER
55
DISPLAY PANEL
18
6
54
MICRO-PROCESSOR (CPU)
48
POWER ON SWITCH
6.2 V
62
61
CONSTANT VOLTAGE
63
ACTUATOR DRIVE CIRCUITRY
65
LOW BATTERY DETECT
62
ACTUATOR
66
53
28
IOML CHAMBER
1
9
COLLECTION BAG

FIG. 13

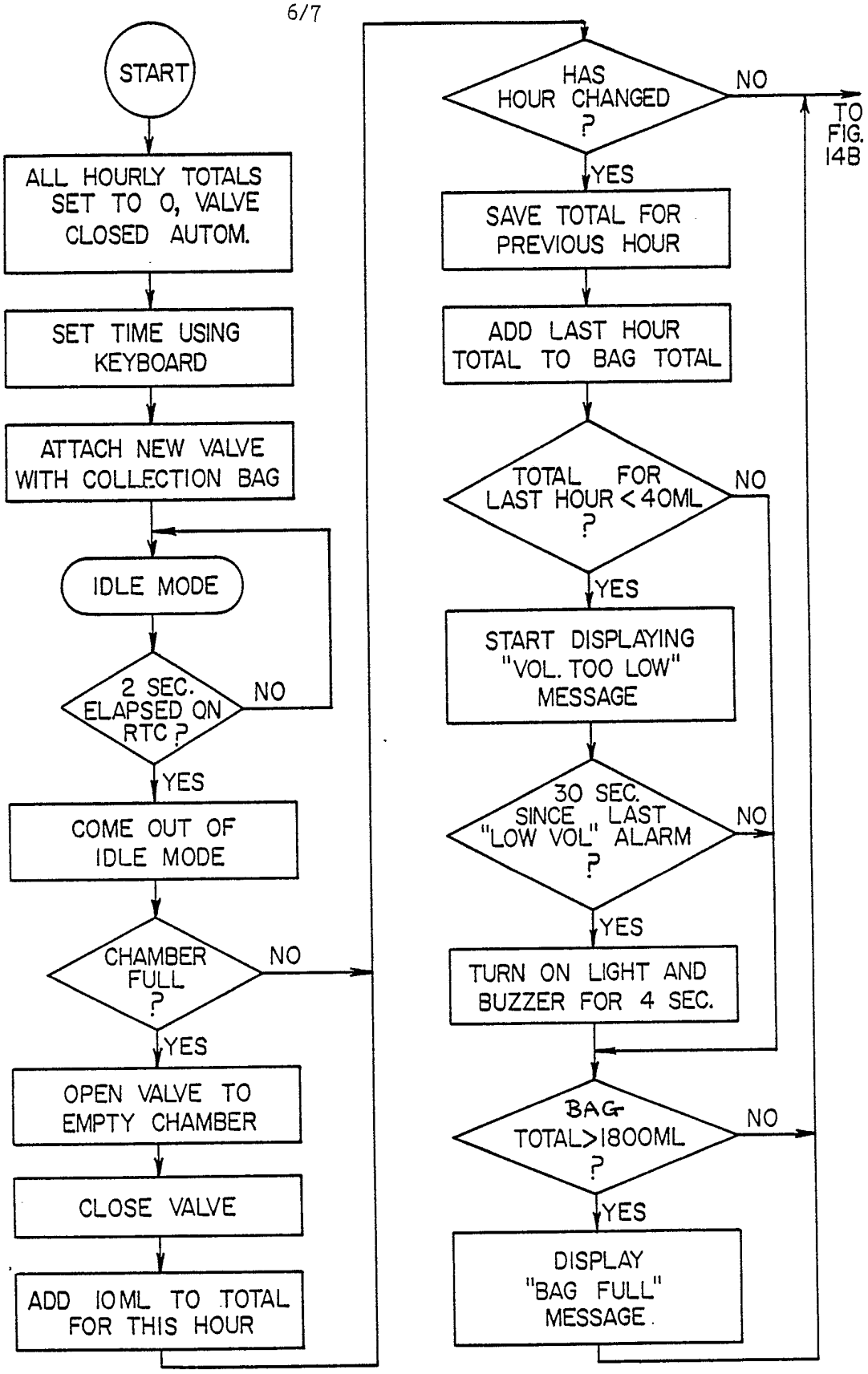
START
ALL HOURLY TOTALS SET TO 0, VALVE CLOSED AUTOM.
SET TIME USING KEYBOARD
ATTACH NEW VALVE WITH COLLECTION BAG
IDLE MODE
2 SEC. ELAPSED ON RTC ?
NO
YES
COME OUT OF IDLE MODE
CHAMBER FULL ?
NO
YES
OPEN VALVE TO EMPTY CHAMBER
CLOSE VALVE
ADD 10ML TO TOTAL FOR THIS HOUR
HAS HOUR CHANGED ?
NO
TO FIG. 14B
YES
SAVE TOTAL FOR PREVIOUS HOUR
ADD LAST HOUR TOTAL TO BAG TOTAL
TOTAL FOR LAST HOUR < 40ML ?
NO
YES
START DISPLAYING "VOL. TOO LOW" MESSAGE
30 SEC. SINCE LAST "LOW VOL" ALARM ?
NO
YES
TURN ON LIGHT AND BUZZER FOR 4 SEC.
BAG TOTAL>1800ML ?
NO
YES
DISPLAY "BAG FULL" MESSAGE.

FIG. 14A

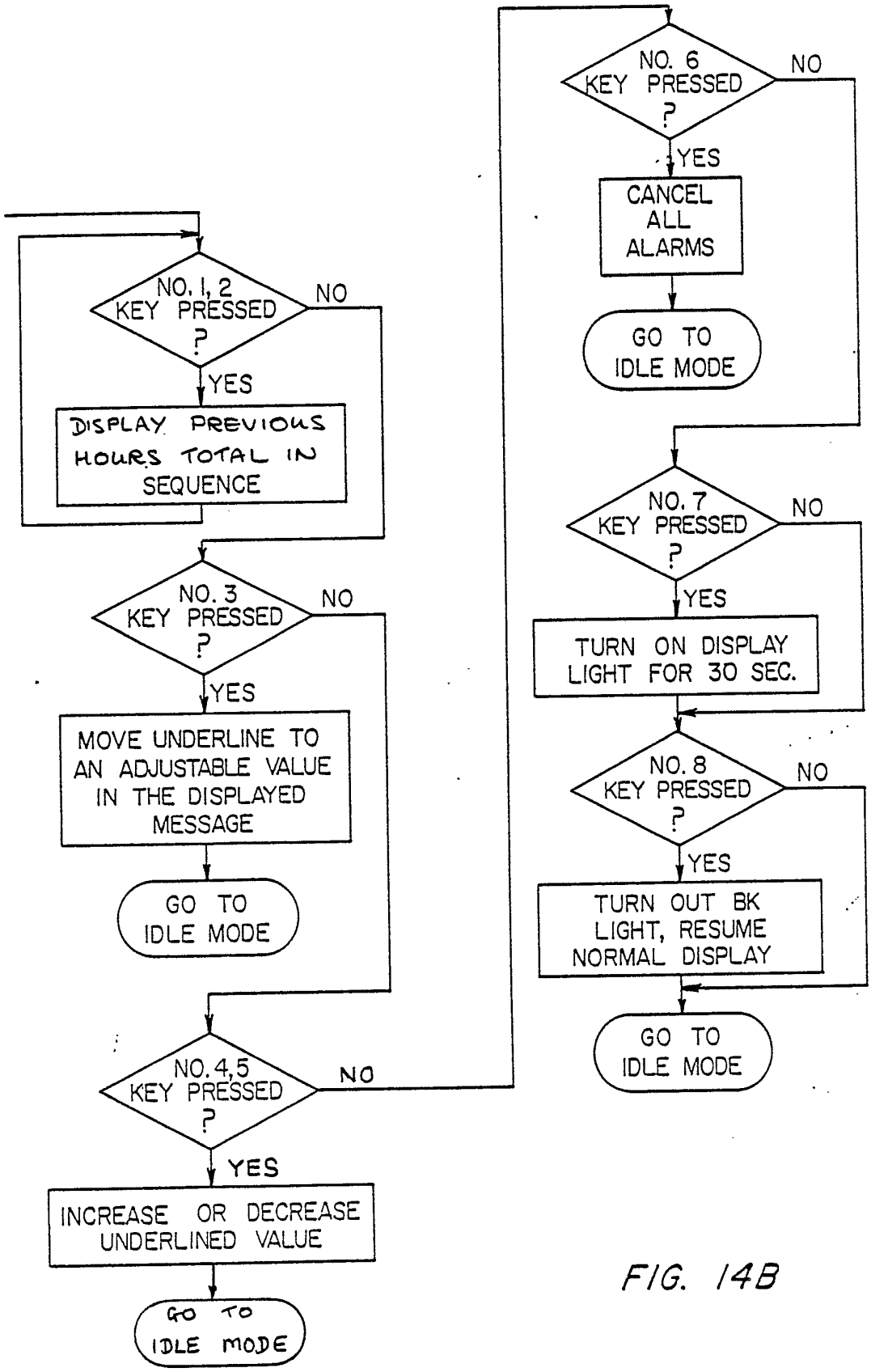
NO. 1, 2 KEY PRESSED ?
NO
YES
DISPLAY PREVIOUS HOURS TOTAL IN SEQUENCE
NO. 3 KEY PRESSED ?
NO
YES
MOVE UNDERLINE TO AN ADJUSTABLE VALUE IN THE DISPLAYED MESSAGE
GO TO IDLE MODE
NO. 4,5 KEY PRESSED ?
NO
YES
INCREASE OR DECREASE UNDERLINED VALUE
GO TO IDLE MODE
NO. 6 KEY PRESSED ?
NO
YES
CANCEL ALL ALARMS
GO TO IDLE MODE
NO. 7 KEY PRESSED ?
NO
YES
TURN ON DISPLAY LIGHT FOR 30 SEC.
NO. 8 KEY PRESSED ?
NO
YES
TURN OUT BK LIGHT, RESUME NORMAL DISPLAY
GO TO IDLE MODE

FIG. 14B

INTERNATIONAL SEARCH REPORT

International Application No PCT/US85/01592

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

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

INT. CL. [4] A61B 5/20; A61M 1/00
U.S. CL. 604/247, 324; 128/760; 250/577; 364/415

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
U.S.	604/246, 247, 253, 256, 65, 66, 322, 323, 324, 325 128/760, 771; 364/415, 707; 73/219, 223 350/331R, 345; 250/227, 577

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

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
A	US, A, Re 26964, Coanda, Published, 13 October 1970	4, 15
Y	US, A, 2,621,808, Blakeney, Published, 16 December 1952	2
A	US, A, 3,065,354, Bird, Published, 20 November 1962	2, 5
Y	US, A, 3,549,893, Gibbs, Published, 22 December 1970	2,3,5,13
A	US, A, 4,223,231, Sugiyama, Published, 16 September 1980	2

* Special categories of cited documents: [15]

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

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
04 October 1985	11 OCT 1985
International Searching Authority [1]	**Signature of Authorized Officer** [20]
ISA/US	R. McDowell RM L. DEWAYNE RUTLEDGE SUPERVISORY PRIMARY EXAMINER

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, 16 with indication, where appropriate, of the relevant passages 17	Relevant to Claim No 18
Y	U.S., A, 4,343,316, Jespersen, Published, 10 August 1982	1,3,4,15-22
Y	U.S., A, 4,532,936, LeVeen et al, Published, 06 August 1985	1,3,4,15-22
Y	N, Journal of Medical Engineering and Technology, Volume 5, No. 4, issued July 1981, Kuhlemeier et al.	1,3,4,15-22