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Apparatus and Method for Measurement of a Parameter of Body Fluid

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FIELD OF INVENTION

This invention relates to an apparatus and method for measurement and display of at least one parameter of body fluid in a patient. In particular, this invention relates to an apparatus and method capable of carrying out measurement and display of urine in a patient.

BACKGROUND OF THE INVENTION

Monitoring of various physiological parameters such as heart rate, blood pressure, temperature and fluid input and output measurements are essential for treatment of patients in intensive care units in hospitals. Urine output volume measurement is one of the main forms of fluid output and is a very critical parameter used in the calculation of fluid balance for a patient. Traditionally, urine output is measured manually using urine collection bags connected to patients via a catheter. Urine volume is recorded manually by nursing staff at fixed intervals. With the advent of computerized clinical information systems ("CIS") in the intensive care units and operating theatres of hospitals, electronic measurements of various physiological parameters and fluid input and output have become essential. To be able to measure urine output volume electronically without significantly increasing the cost of measurement (compared to traditional urine bags) has been a real challenge for those in the medical field.

At the present time, commercially available electronic urine volume measurement units (hereinafter referred to as "urimeters") make use of custom-made collection containers so as to be compatible with the CIS systems and other associated technology used for these systems. These custom-made containers are



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disposable (in line with hospital infection control policy and requirements) and they are considerably more expensive compared to previously used urine bags.

A desired objective of this invention is to design and develop an apparatus or instrument that is capable of measuring the volume and other parameters of body fluids such as urine electronically using standard, commercially available urine bags. Thus, it is envisaged that there should be a minimal need for using any custom-made collection containers if an apparatus of this type is developed. The apparatus preferably should also have the capability to interface with any computerized CIS for data transfer, enabling auto charting of patient's urine output volume and other desired parameters. By using standard urine collection bags, the operating cost of such an apparatus is kept to a minimum.

SUMMARY OF INVENTION

In accordance with a first aspect of this invention, there is provided an apparatus for measurement of body fluids comprising a measuring sensor, a cassette-type holder for the urine collection bag and electronic equipment for measurement, display and other monitoring features.

In accordance with a second aspect of this invention, there is provided a method of measuring and displaying at least one parameter of body fluid produced by a catheterised patient comprising the steps of:

- attaching a urine bag within a housing to a discharge tube which is in fluid communication with the patient,
- collecting the body fluid from the patient in the urine bag,
- weighing the body fluid collected in the urine bag so as to form an analog signal,
- converting the analog signal to a digital signal so as to form a digital input,
- inputting the digital input of the weight of the urine bag into a micro controller,
- calculating the at least one parameter in the micro controller; and

- displaying the at least one parameter on a display means.

Typically, the method further comprises the step of providing a portable power source to power the micro controller.

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Typically, the housing maintains the urine bag in a substantially upright position and comprises a lockable entry means to prevent unauthorised access to the urine bag.

- 10 Typically, the at least one parameter includes the present volume, total volume and flow rate of the body fluids.

Typically, the housing comprises a movable tray or a cassette holder device.

- 15 Typically, the method according to the second aspect of this invention, further comprises the step of activating an alarm if the calculated at least one parameter falls outside preset values stored in the micro controller.

- 20 Typically, the method according to the second aspect of this invention further comprises the step of transferring data regarding calculated parameter values to a remote computerised system for monitoring, logging and recording of the parameters associated with the patient.

- 25 Typically, the method further comprises the step of providing a fail-safe means, which alerts the micro controller to stop processing parameters when the lockable entry means is disturbed.

Typically, in the method and apparatus of this invention the body fluid is urine.

- 30 In accordance with a third aspect of this invention, there is provided an apparatus for measuring and displaying at least one parameter of body fluid produced by a catheterised patient comprising:

- a discharge hose in fluid communication with the patient,

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- a urine bag for collecting the body fluid from the patient and which is suspended within a housing,
- means for weighing the body fluid in the urine bag and which is capable of forming an analog signal,
- 5 - means for converting the analog signal to a digital signal so as to form a digital input,
- means for inputting the digital input of the weight of the urine bag into a micro controller,
- means for calculating the at least one parameter in the micro controller;
- 10 and
- means for displaying the required at least one parameter on a display means.

15 Typically, the apparatus according to the third aspect of this invention further comprises a portable power source.

Typically, the housing of the apparatus maintains the urine bag in a substantially upright position and comprises a lockable entry means to prevent unauthorised access to the urine bag.

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Typically, the at least one parameter includes the volume, flow rate, etc of the body fluid.

25 Typically, the apparatus according to a third aspect of this invention further comprises a means for activating an alarm if the calculated at least one parameter falls outside preset values stored in the micro controller.

30 Typically, the apparatus according to the third aspect of this invention further comprises a means for transferring data regarding calculated parameter values to a remote computerised system for monitoring, logging and recording of the parameters associated with the patient.

Typically, the apparatus further comprises a fail-safe means, which alerts the micro controller to stop processing parameters when the lockable entry means is disturbed.

- 5 Typically, the apparatus comprises a housing, which further comprises a movable tray or a cassette holder type device.

10 In accordance with a fourth aspect of this invention, there is provided a method of measuring and displaying at least one parameter of urine produced by a catheterised patient comprising:

- attaching a urine bag within a housing having a lockable entry means to a discharge tube which is in fluid communication with the patient,
- suspending the urine bag in the housing such that the urine bag hangs freely,
- 15 - collecting the urine from the patient in the urine bag,
- weighing the urine bag with a weighing means which comprises a measuring sensor which produces an analog signal,
- converting the analog signal to a digital signal,
- inputting the digital signal into a micro controller so as to calculate at least one parameter of the urine,
- 20 - providing a fail-safe means which alerts the micro controller to stop processing parameters when the lockable entry means is opened, and
- displaying the required at least one parameter of the urine on a display means.

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In accordance with a fifth aspect of this invention, there is provided an apparatus for measuring and displaying at least one parameter of urine produced by a catheterised patient comprising:

- means for attaching a urine bag within a housing having a lockable entry means to a discharge tube which is in fluid communication with the patient,
- 30 - means for suspending the urine bag in the housing such that the urine bag hangs freely,

- means for collecting the urine from the patient in the urine bag,
- means for weighing the urine bag with a weighing means which comprises a measuring sensor which produces an analog signal,
- means for converting the analog signal to a digital signal,
- 5 - means for inputting the digital signal into a micro controller so as to calculate at least one parameter of the urine,
- means for providing a fail-safe means which alerts the micro controller to stop processing parameters when the lockable entry means is opened, and
- means for displaying the required at least one parameter of the urine on a
- 10 display means.

Typically, the measurement in the apparatus is carried out using a weighing means such as a load cell that weighs the urine bag with the urine. Typically, the

15 weight is then converted to volume by the micro controller and the readings are displayed on a front panel of liquid crystal display means.

Typically, a user such as a hospital caregiver is able to set the interval of measurement, depending on the requirement of each patient. This is achieved by

20 a timing means which typically forms part of the apparatus and method of this invention.

Typically, the apparatus is also capable of displaying parameters such as current volume and cumulative volume over a period of time. Typically, the apparatus

25 calculates the urine flow rate based on the volume measurements.

Typically, the user or caregiver also is able to set the parameters for an alarm warning in case of high or low flow rates. For example, when the patient's urine flow rate falls outside the high-low range pre-set by the user, the unit gives an

30 audible and visual alarm/warning. This enables the doctors to initiate any medical action required.

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Typically, the apparatus is a unit which is designed as a portable unit with a battery back up. Typically, the battery is internally charged when the unit is plugged to mains alternating current (A.C.) supply.

5 Typically, the housing of the apparatus is a cassette-type holder for the urine bag which is designed and built in such a way that the urine bag is hung freely, enabling an accurate weight measurement by the load cell. Typically, the cassette-type holder also prevents any fluctuations in the measurements that may
10 arise from the urine bag swinging during transportation or any other accidental disturbance of the equipment by maintaining the urine bag in a substantially upright position.

Typically, the front panel display means of the apparatus or unit is angled to facilitate comfortable viewing of all displayed parameters and alarm messages to
15 users and caregivers, when the apparatus or unit is placed on the floor by the patient's bedside.

Typically, the urine bag holder is able to accommodate a wide variety of standard commercially available urine bags and holding hooks are adjustable to suit
20 different sized bags.

Typically, the apparatus is equipped with features to prompt the user for a systematic step-by-step procedure to detach the bag or to empty the contents of the bag, so that measurement can be suspended and resumed when ready. This
25 avoids any loss of measurement data during such instances.

Typically, all the measured and calculated parameters (current urine volume, cumulative volume, flow rate) and other relevant information such as date of measurement, time of measurement and alarm information can be digitally
30 transferred to any remote computerised system such as CIS used in the hospital.

Brief Description Of Drawings

5 This invention will now be described, by way of example only, with reference to the accompanying drawings, which are incorporated into and constitute a part of the description of the invention. The drawings serve merely to illustrate
embodiments of the invention and should not be considered as limiting the scope of the invention.

10 Fig.1 is a block diagram of the urine bag and electrical components of the apparatus in accordance with a first embodiment of this invention;

Fig.2 (a) is a flow chart illustrating the operation of the initialization steps of the apparatus as shown in Figure 1;

15 Fig. 2(b) is a flow chart illustrating in more detail the steps of the apparatus and method of this invention;

20 Fig. 3(a) is a flow chart illustrating the operation of the apparatus when the urine bag is drained and transported in accordance with a second embodiment of this invention,

Fig. 3(b) is a flow chart illustrating the operation of the apparatus when the urine bag is drained and transported in accordance with a third embodiment of the invention; and

25 Fig. 4 is a perspective view of a housing of an apparatus in accordance with a fourth embodiment of this invention.

Description of the Embodiments of the invention

30 Fig 1 is a block diagram of the urine bag and electrical components of the apparatus in accordance with a first embodiment of this invention. Fig.1 shows the proposed set-up of the entire system and apparatus (20). The apparatus (20) comprises of a master micro controller (34), a measuring or weighing sensor

(46), electronics set-up for measurement (42), an analog to digital converter (40) for converting the analog signal to a digital signal, memory means (32), a fail-safe electro mechanism (30),
a keyboard (28), a LCD display (26), a Real Time Clock (24), a slave controller
5 (22), a power supply unit (38) and a battery (36).

At power up, the micro controller (34) does a self-test and initialises the system to a default state. The micro controller (34) then checks for the presence of a urine bag (44). If the urine bag (44) is present the micro controller (34) informs
10 the operator to replace the old urine bag (44), or else to connect a new urine bag (44). Once a new urine bag (44) is connected, the weight of the urine bag (44) is measured using the weighing sensor (46) and tarred.

Then, the micro controller (34) periodically measures the weight of the urine bag
15 (44) as measured by the weighing sensor (46) and accumulates the incremental change. Thus, an accumulated value for the weight of the urine bag (44) is converted into the corresponding volume using a suitable factor. Then the calculated volume is used further to calculate other parameters such as cumulative volume, flow rate, etc. The value is updated on a liquid crystal
20 display (LCD) (26) and transmitted to a computerized clinical information system (CIS) through a slave controller (22). The micro controller (34) periodically checks for an alarm limit violation and activates the alarm functions.

A Real Time Clock (24) provides various timing functions for the system. A user
25 or caregiver is able to interact with the apparatus (20) through a keyboard (28). A sensor (46) such as a load cell is used for various weight measurements. An analog to digital converter (40) is used for converting the analog signal into the corresponding digital signal, so that the micro controller (34) is able to process the signal generated by the sensor (46).

A fail-safe electro mechanism (30) asynchronously is activated when there are intrusions such as door, cassette openings to a housing (not shown) and interrupts the micro controller (34) for necessary actions.

5 A power supply unit (38) converts the mains power to appropriate potentials as required by various parts of the system. The power supply (38) intelligently charges a battery (36), which provides back up power in the absence of mains power. The power supply unit (38) may also be a portable power unit.

10 In Fig.2 (a), there is shown a flow chart illustrating the initialisation steps for the operation of the micro controller (34) upon powering up. A self-test for the micro controller (34) is initialised whereby if the self-test is not passed then an error message is produced on the Liquid crystal display (LCD) and the operation ends. Otherwise, if the self-test is passed then the apparatus (20) is set to a
15 default value and a time interval is able to be inputted by a user by way of the keyboard (28).

In figure 2 (b), there is shown a flow chart illustrating in more detail the operation of the apparatus and method of this invention.

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In particular, there is shown a more detailed flow chart illustrating the steps involved in the operation of the calculation of the parameters using the microprocessor (34) after the initialisation test is passed as shown in Fig.2(a).

25 As described above, when the initialisation test is passed as shown in Fig.2(a) the micro controller (34) requests whether the urine bag (44) is connected to the measuring and weighing sensor (46) and the movable tray or cassette type device. If the urine bag (44) is not connected then the micro controller (34) measures values where there is no urine bag (44) connected to the measuring sensor (46)
30 and requests that a new urine bag (44) be connected to the measuring sensor (46). If the urine bag (44) is connected to the weighing sensor (46) then the display (26) requests the user to connect a new urine bag (44). As described above, once

a new urine bag (44) is connected, the weight of the urine bag (44) is measured using the weighing sensor (46) and tarred.

In particular, the following steps are now performed:

- 5 - Initialise all parameters,
- Store a copy of all parameters,
- A slave processor is activated for data communication to a remote computerised system, for example CIS system, and
- Initialise all the display windows.

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After the above steps have been performed the micro controller (34) monitors whether the weight of the urine bag (44) is increased. As shown in the flow chart if the urine bag (44) weight is increased then the new bag weight is calculated as the old bag weight in addition to the incremental change in weight. This value is
15 converted from an analog to a digital signal and the micro controller (34) calculates the volume of the urine in the urine bag (44) by calculating the appropriate equation.

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After the new urine bag (44) weight and volume are calculated, the display (26) is updated and displays the new values for the parameters, "PRESENT VOLUME", "TOTAL VOLUME", and "FLOW RATE".

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The micro controller (34) also monitors whether the new calculated parameters exceed the preset values stored on the micro controller (34). If the new calculated parameters exceed the preset values then an alarm limit violation occurs and an audible alarm is activated together with a visual alarm warning on the display (26). If the new calculated parameters do not exceed the preset values then the micro controller (34) determines whether a suitable time interval is over and then proceeds to calculate the previous volume and the present volume.

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After this step is performed the previous volume is then reset to zero.

In Fig.3(a) there is shown a flow chart illustrating the operation of the apparatus when the urine bag is drained and transported in accordance with a third embodiment of this invention.

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Figure 3(a) is a flow chart of the steps performed when the door of the housing, which contains the urine bag (44), is opened or otherwise interrupted and transport of the patient is required. As shown in the attached representation the micro controller (34) proceeds to lock all values for each parameter. The display (26) then requests the user as to whether the urine bag (44) has to be drained and if so then proceeds with the bag draining procedure. If chosen to drain, display (26) shows the message "Drain the bag and press ENTER to confirm". In order for the micro controller (34) to proceed the user is required to press 'Enter' to confirm that the urine bag (44) has to be drained. Upon receiving this confirmation, the micro controller (34) checks whether the bag is drained. If drained, the display (26) shows the message "Bag drained. Close the door. Press ENTER to continue". Upon receiving the suitable confirmation the micro controller (34) will now proceed to update values for each parameter. If the urine bag (44) is not to be drained then the user is requested whether the bag has to be transported with the patient. If the bag has to be transported with the patient, then the user proceeds with the transport procedure and the display (26) shows the message "Ready to Transport" and the micro controller (34) checks whether the urine bag (44) is removed. If the urine bag (44) is removed, then the display (26) shows the message "Transport Mode...Hang the bag and Press ENTER to continue". Whilst in the transport mode, the micro controller (34) updates parameters such as time and monitors whether the bag is connected again. If connected, the micro controller (34) completes the transport procedure and reverts to normal operating mode.

30 In Figure 3(b) there is shown a similar sequence of steps as shown in Fig. 3 (a) except that the steps for draining the urine bag (44) are shown. The procedure is similar to the procedure as shown in Figure 3 (a) except that upon inputting "yes"

to the question of "Is bag drain?", the micro controller (34) measures current values for the weight of the urine bag (44) from the sensor (46). There after, the message " Drain the bag and press ENTER to confirm" appears on the display (26). Afterwards, the micro controller checks if the bag is drained. If drained, the display shows the bag is drained and the parameters are updated.

In Fig.4, there is shown a housing for the apparatus of this invention in accordance with an embodiment of this invention. The housing 100 has an upper end 108 and a lower end 110 together with a pair of sidewalls 105 and a rear wall (not shown). The front of the housing 100 comprises a pair of doors 102 and 103 respectively. A display 104 is also provided and is disposed in a manner such that it is easily visible to a user who wishes to view the display (104).

In use, the urine bag is placed within the housing (100) so that it is upright and is suspended freely within the housing (100). The electrical components are described in the previous embodiments and are connected to the housing and urine bag (44) together with the weighing sensor (46). The method and apparatus steps are as previously described.

Modifications and variations such as would be apparent to those skilled in the art are deemed to be within the scope of this invention. It is to be understood that this invention should not be restricted to the specific embodiment(s) described above.

Claims

1. A method of measuring and displaying at least one parameter of body fluid
5 produced by a catheterised patient comprising the steps of:
- attaching a standard urine bag within a housing to a discharge tube which
is in fluid communication with the patient,
 - collecting the body fluid from the patient in the standard urine bag,
 - 10 - weighing the body fluid collected in the standard urine bag so as to form
an analog signal,
 - converting the analog signal to a digital signal so as to form a digital
input,
 - inputting the digital input of the weight of the standard urine bag into a
15 micro controller,
 - calculating the at least one parameter in the micro controller; and
 - displaying the at least one parameter on a display means.
2. A method according to claim 1, further comprising the step of providing a
20 portable power source to power the micro controller.
3. A method according to claim 1, wherein the housing maintains the standard
urine bag in a substantially upright position and comprises a lockable entry
means to prevent unauthorised access to the standard urine bag.
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4. A method according to claim 1, wherein the at least one parameter includes
the present volume, total volume and flow rate of the body fluid.
5. A method according to claim 1, wherein the housing comprises a movable
30 tray or a cassette holder device.

6. A method according to claim 1, further comprising the step of activating an alarm if the calculated at least one parameter falls outside preset values stored in the micro controller.
- 5 7. A method according to claim 1, further comprising the step of transferring data regarding calculated parameter values to a remote computerised system for monitoring, logging and recording of the parameters associated with the patient.
- 10 8. A method according to claim 3, further comprising the step of providing a fail-safe means which alerts the micro controller to stop processing parameters when the lockable entry means is disturbed.
9. An apparatus for measuring and displaying at least one parameter of body fluid produced by a catheterised patient comprising:
- 15 - a discharge tube in fluid communication with the patient,
- a standard urine bag for collecting the body fluid from the patient and which is suspended within a housing,
- means for weighing the body fluid in the standard urine bag and which is capable of forming an analog signal,
20 - means for converting the analog signal to a digital signal so as to form a digital input,
- means for inputting the digital input of the weight of the standard urine bag into a micro controller,
- means for calculating the at least one parameter in the micro controller;
25 and
- means for displaying the required at least one parameter on a display means.
10. An apparatus according to claim 9, further comprising a portable power
30 source.

11. An apparatus according to claim 9, wherein the housing maintains the standard urine bag in a substantially upright position and comprises a lockable entry means to prevent unauthorised access to the standard urine bag.
- 5 12. An apparatus according to claim 9, wherein the at least one parameter includes the volume, flow rate, etc of the body fluids.
13. An apparatus according to claim 9, wherein there is further provided a means for activating an alarm if the calculated at least one parameter falls outside preset
10 values stored in the micro controller.
14. An apparatus according to claim 9, further comprising a means for transferring data regarding calculated parameter values to a remote computerised system for monitoring, logging and recording of the parameters associated with
15 the patient.
15. An apparatus according to claim 9, wherein the housing comprises a movable tray or a cassette holder type device.
- 20 16. An apparatus according to claim 11, wherein there is further provided a fail-safe means which alerts the micro controller to stop processing parameters when the lockable entry means is opened,
17. An apparatus according to claim 9, wherein the body fluid is urine.
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18. A method of measuring and displaying at least one parameter of urine produced by a catheterised patient comprising:
- attaching a standard urine bag within a housing having a lockable entry means to a discharge tube which is in fluid communication with the patient,
 - 30 - suspending the standard urine bag in the housing such that the standard urine bag hangs freely,
 - collecting the urine from the patient in the standard urine bag,

- weighing the standard urine bag with a weighing means which comprises a measuring sensor which produces an analog signal,
- converting the analog signal to a digital signal,
- inputting the digital signal into a micro controller so as to calculate at least one parameter of the urine,
- providing a fail-safe means which alerts the micro controller to stop processing parameters when the lockable entry means is opened, and
- displaying the required at least one parameter of the urine on a display means.

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19. An apparatus for measuring and displaying at least one parameter of urine produced by a catheterised patient comprising:
- means for attaching a standard urine bag within a housing having a lockable entry means to a discharge tube which is in fluid communication with the patient,
 - means for suspending the standard urine bag in the housing such that the urine bag hangs freely,
 - means for collecting the urine from the patient in the standard urine bag,
 - means for weighing the standard urine bag with a weighing means which comprises a measuring sensor which produces an analog signal,
 - means for converting the analog signal to a digital signal,
 - means for inputting the digital signal into a micro controller so as to calculate at least one parameter of the urine,
 - means for providing a fail-safe means which alerts the micro controller to stop processing parameters when the lockable entry means is opened, and
 - means for displaying the required at least one parameter of the urine on a display means.
20. An apparatus for measuring and displaying at least one parameter of body fluid produced by a catheterised patient according to claim 15, wherein the housing is a cassette holder type device.

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