

PERITONEAL DIALYSIS MACHINE

FIELD OF INVENTION

5 The invention relates generally to a machine that performs dialysis for patients who have reduced kidney function. More specifically, the invention concerns a peritoneal dialysis cyclor that performs peritoneal dialysis (PD) for patients who experience renal failure.

BACKGROUND OF THE INVENTION

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When a patient experiences renal failure, his kidneys are no longer capable of filtering his blood to remove metabolic byproducts and excess fluid. As such, the patient needs to undergo dialysis where a machine functions as a partial replacement for the patient's ailing kidneys. There are two main types of dialysis: (1) hemodialysis and (2) peritoneal dialysis.

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When a patient undergoes hemodialysis, the patient's blood is circulated extracorporeally where fluid and soluble waste products are removed by osmosis through the use of an artificial membrane. The treatment is usually carried out in a hemodialysis center, often a hospital, due to the complexity of the machine and procedure. This stands in contrast to
20 the normal procedure for peritoneal dialysis, which can be done in many other locations.

With peritoneal dialysis, a hypertonic solution is pumped into interstitial space between the patient's organs and the patient's abdominal wall. The solution draws out plasma in the patient's blood which carries with it metabolic waste products. Then the solution is pumped out
25 of the patient, ridding the patient of said waste products and some surplus fluid. Two major peritoneal dialysis modalities exist – Continuous Ambulatory Peritoneal Dialysis (CAPD) or Automated Peritoneal Dialysis (APD) with CAPD being performed manually at intervals throughout the day and APD being performed by a machine, called a cyclor, at night. As peritoneal dialysis is a self-administered mode of treatment, the patients can adjust their
30 treatment according to their own schedule and are, in general, more free to engage in ordinary daily activities such as work.

As with most other types of dialysis, continual monitoring of the patient's fluid balance is necessary since, unlike normally functioning kidneys, dialysis machines are not capable of dynamically modifying the treatment regimen to adjust for environmental factors and changes in daily fluid intake. Excess fluid poses a danger since it can lead to cardiac complications. Since
5 peritoneal dialysis is, however, performed outside the supervision of medical personnel, it falls to the patients to record and report their fluid balances, which are usually observed through proxy measurements of blood pressure and weight. Patient compliance is vital to the success of the therapy.

10 Issues with patient compliance are not specific to dialysis treatments – they are endemic in most unsupervised medical therapies. See e.g. Is This Patient Taking the Treatment as Prescribed?, Journal of the American Medical Association, 1993;269(21)-2779-2781 (indicating that “noncompliance is common” for self-administered treatments – this can be extended to self-administered monitoring). With regard to monitoring in particular, patients who observe
15 deterioration in their monitored indices may be strongly adverse to continued monitoring, a cyclical process which leads to even poorer health outcomes.

Ameliorating compliance issues through frequent visits by medical professionals tends to reduce one of the primary benefits of peritoneal dialysis which is the labor savings in letting the
20 patients care for themselves instead of going to a hospital.

In the journal Peritoneal Dialysis International, Volume 27 (2007), pp. 521-526, Telemedicine System For Patients On Continuous Ambulatory Peritoneal Dialysis, there is disclosed a telemedicine system that monitors a patient undergoing automated peritoneal
25 dialysis. It consists of a data transport system and a view-send system (video-conferencing). Using the video-conferencing, the patient can talk face to face with the physician in a hospital.

United States patent application no. 2009/0275883 discloses a peritoneal dialysis system which calculates a peritoneal dialysis dwell time. The system includes a processor for
30 operating a peritoneal dialysis machine, a memory of the processor or a memory accessible to the processor, the memory storing a look-up table containing peritoneal dialysis input parameters, peritoneal dialysis therapy outcomes, and peritoneal dialysis dwell times corresponding to the input parameters and dwell times, and a software program stored in the memory of the processor or the memory accessible to the processor for receiving a selection or

an input of at least one desired therapy outcome of a patient and calculating a dwell time for the patient for optimizing the at least one peritoneal dialysis therapy outcome for the patient.

There is thus an unfulfilled need for a peritoneal dialysis machine that is able to monitor
5 patient compliance behavior and remedy any lapses in the shortest time possible. Patient's compliance and monitoring of weight and blood pressure data are vital to ensure good medical outcomes for patients on dialysis. The present invention was developed in consideration of these needs.

10 SUMMARY OF THE INVENTION

In one aspect, the invention provides a peritoneal dialysis (PD) machine comprising:
a blood pressure monitor;
a weight scale;

15 means for recording in the machine, measurements of a patient's blood pressure and weight taken using the blood pressure monitor and scale;
means for monitoring the frequency with which such measurements are recorded; and
means for generating a local and/or remote alert when the frequency of recording the measurements does not comply with a predetermined schedule.

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In an embodiment, an event is logged in the PD machine each time the frequency of recording the measurements does not comply with a predetermined schedule.

In another embodiment, PD machine is adapted to maintain a count of the number of
25 consecutive non-compliance events.

The type of alert generated may be dependent upon the value of the count.

In a further embodiment, the count is resettable manually.

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In one embodiment, PD machine comprises a communication module for transmitting a remote alert.

The communication module may be of wireless type, for example using a cellular network.

In another embodiment, the communication module automatically transmits a remote
5 alert or event to a server or mobile terminal device.

In a further embodiment, the communication module allows for communication between the patient and a medical personnel.

10 The communication may be through text-based messages and instructions that are displayable on a monitor display of the PD machine.

Alternatively, or additionally, the communication module may comprise a voice modem which allows a medical personnel to communicate verbally with the patient.

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In yet a further embodiment, visual information is generated on a monitor display of the PD machine to inform the patient of the non-compliance.

Such visual information may include an educational video presentation.

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The present invention seeks to improve the success of a peritoneal dialysis therapy by improving the patient's compliance through the use of an integral blood pressure monitor and scale and automatic monitoring of the measurements taken by the patient. The invention provides a solution for a peritoneal dialysis (PD) machine to perform multiple functions of
25 recording, storing, and monitoring measurements of a patient's blood pressure and weight. The peritoneal dialysis (PD) machine is physically integrated and connected to a blood pressure monitor and scale. The blood pressure monitor and scale are powered by the PD machine. Advantageously, the integral nature of the blood pressure monitor and scale in the PD machine permits real-time monitoring of patient's compliance where any non-compliance can be
30 immediately detected by the machine and the machine can take the requisite action by generating an alert. This provides the behavioral benefit that lapses are not permitted to solidify into habits and prevents the patient from being able to falsify logs, something that tends to occur when the patient is asked to do manual recordation.

The preferred method of sampling a patient's blood pressure is to measure it while the patient is sitting and take three measurements in-order to eliminate transient changes in the detected pressure.

- 5 In one embodiment, when the frequency of recording the patient's measurement does not comply with a predetermined schedule, in other words when non-compliance is detected, a local and/or remote alert is generated. Based on the recommended treatment or solutions pre-configured in the PD machine, the PD machine takes the requisite action to address the non-compliance. Based on a predetermined sum of consecutive non-compliance events leading to
- 10 the present event, the PD machine is preconfigured to either display a local alert to prompt the patient or display an educational video or initiate a remote alert to notify the nurse who can then call into the PD machine to speak to the patient directly. The PD machine may be adapted to maintain a count of number of consecutive non-compliance events where the type of alert generated is dependent upon the value of the count. The count may be resettable manually.
- 15 The non-compliance event and the intervention are logged and stored in the internal database of the PD machine.

- In another embodiment, when the patient fails to record his bodyweight and blood pressure before therapy, the PD machine generates a local alert that is logged and stored in the
- 20 internal database of the machine for referral purposes. The storing of this information is helpful to assist the physician who is monitoring the patient's condition on a pre-determined scheduled visit where close monitoring of the collected data permits the physician to adjust his patient-interaction to improve the patient's compliance on PD therapy.

- 25 In another embodiment, when a patient chooses to abort a PD therapy, the instructions to abort are automatically stored in the PD machine for record purposes. This information is transmitted wirelessly to a central server on daily basis, together with the summary treatment information.

- 30 In another embodiment, the patient's pre-therapy and post-therapy weight is measured using the weight scale and stored in the PD machine in order to ensure that during the course of the therapy, excess fluid is not permitted to remain in the patient. As a safety feature of the PD machine, on detecting such excess fluid, the PD machine generates an alert to prompt the patient where prior to disconnecting from the PD machine, a manual drain sequence is to be

initiated to prevent excess fluid accumulation. Fluid accumulation is a material issue in the use of automatic cyclers that do not require a complete drain on each cycle. The remote alert may also be sent to the nurse or physician using a mobile device.

5 A practitioner of ordinary skill in the art will appreciate that there are a variety of methods in which the blood pressure monitor and scale and the PD machine may transmit data where the best mode will vary with the specific implementation selected. These include the use of proprietary protocols or virtualized serial ports. Both parameters are stored in an on-board database and may or may not be transmitted to a central server or directly to the physician
10 through a communication module.

In another embodiment, the PD system involves the physical integration of the blood pressure monitor and scale electronics with the peritoneal dialysis machine to form an integral unit and are connected internally using a physical cable to an internal Recommended Standard
15 232 (RS-232) serial header combined with an external scale connected over Universal Serial Bus (USB). This provides the potential benefit of supplying power to the blood pressure monitor or scale as well as purveying data from the blood pressure monitor or scale.

In the above embodiments, the local alert may take various forms including any one or
20 more of a visual warning such as an indicator on the machine, an audible warning such as a buzzer or beeping loudspeaker, and the presentation of textual and/or image-based instructions to the patient on a display monitor of the device.

A remote alert in the above embodiments is preferably transmitted through a
25 communication module integral to the PD machine. The communication module is preferably of wireless type and may make use of cellular wireless network protocols such as GSM, 3G, WiMax, LTE to transmit the data. In its simplest form, the alert may be transmitted using the Short Message Service (SMS) or Multimedia Message Service (MMS) directly to the physician or other medical personnel such as a standby nurse. Such messages may contain data to
30 inform of the patient's readings, or simply inform the recipient of the event and direct the same to a web server from which full details can be retrieved.

Aside from the generation of remote alerts, the communication module preferably sends the patient's data reading to the web server on a regular, for example, daily basis. The

communication module may also send the patient's data to a mobile terminal device. In this way, the physician can check and assess the patient's progress and condition at any time. The data may be transmitted using wireless protocols such as MMS, GPRS, EDGE, HSPA, HSPA+ and the like.

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Preferably, the communication module allows two-way communication, whereby a doctor may request, in real time and over-the-air, the PD machine to retrieve and view the latest recorded patient data. The communication module may allow the remote sending of instructions to the patient on how to correct or modify their treatment. For example, the machine may
10 present text or other forms of instruction messages on the display monitor of the machine, in response to commands received from a remote source via the communication module.

In another embodiment, the communication module includes a cellular voice modem that allows a doctor or nurse to speak directly with the patient through dialing-up to the PD machine.
15 This allows the medical personnel to immediately check up on any problems the patient may be facing. The use of a voice modem is preferable over text-based messages and instructions, in the case of non-literate or less literate patients.

BRIEF DESCRIPTION OF THE DRAWINGS

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The invention is illustrated, though not limited, by the following detailed description of embodiments thereof, when taken in conjunction with the accompanying drawings.

In the drawings, like reference signs are used to denote like parts throughout the several
25 views. The features of the described embodiments are generic to all embodiments unless specifically stated otherwise or required by the context.

Fig. 1 is a perspective view of a peritoneal dialysis (PD) machine in accordance with an embodiment of the invention.

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Fig. 2 is a schematic block diagram showing the main hardware and software components of the peritoneal dialysis (PD) machine.

Figs. 3(a) and 3(b) are screenshots on the display of the machine when the patient takes measurements of weight and blood pressure, respectively.

Fig. 4 is a flow chart that illustrates the process of recording and monitoring a patient's data and generating alerts in accordance with an embodiment of the invention.

Fig. 5 is a flow chart of the process of communicating alerts according to the degree of non-compliance by the patient.

Fig. 6 is a flow diagram that illustrates communication to and from the PD machine.

DETAILED DESCRIPTION OF THE EMBODIMENTS

Figure 1 illustrates in a perspective view, the first embodiment of a Peritoneal Dialysis (PD) machine 10 with the components of a blood pressure monitor 1 and a weight scale 2. On the front side of the PD machine, there is a power button which is used in order to control and reset the operating condition of the PD machine 10. The machine suitably incorporates a touch screen panel (Figure 2) for the user to input commands to the PD machine 10. Alternatively, a physical keypad or a touch screen interface that is integral to the monitor display (Figure 2), may be provided for this purpose.

The weight scale 2 is positioned at the bottom of the PD machine 10 which allows weighing to be done. It functions to measure the patient's pre-therapy and post-therapy weight. The measurements taken are stored in the internal database of the PD machine 10. In one cycle, the comparison of the patient's weight measurement during pre-therapy and post-therapy allows the monitoring for any excess fluid remaining in the patient after the PD therapy.

The blood pressure monitor 1 measures and monitors the blood pressure of the patient undergoing the PD therapy. Preferably, the patient's blood pressure is measured while the patient is in a sitting position and three measurements are taken in order to eliminate transient changes in the detected pressure. The PD machine 10 receives data from the blood pressure monitor 1 and stores the collected data in the internal database of the PD machine 10.

The blood pressure monitor 1 consists of an arm cuff and a hose for connecting the cuff to the machine through a suitable plug/socket which is subsequently connected to a compressor with integral pressure sensors. Preferably, the electronics that computes the pressure readings is built inside the machine, so that the cuff and hose are of lower cost and can be replaced if
5 necessary due to damage or wear-and-tear.

Prior and post to every PD treatment, the patient's blood pressure and weight are measured. The threshold of the frequency of recording the patient's measurements is defined by the limit of how many times the patient is not recording the measurements during the PD
10 therapy. Once the threshold is exceeded, the PD machine 10 generates an alert. The alert may take various forms including any one or more of a visual warning such as an indicator in the form of a flashing light on the machine. The alert may also be in the form of an audible warning such as a buzzer or beeping loudspeaker, and the presentation of textual and/or image-based instructions to the patient on the display of the PD machine 10.

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Referring to Figure 2, for the hardware components of the PD machine 10, the preferred embodiment utilizes an x86 single board computer (SBC) 5 with at least one USB port 6 and at least one RS-232 port 7, for example, a SBS-CDM1351 manufactured by SBS Science and Technology Co., Ltd. A USB scale 2 is powered by and communicates with the single board
20 computer SBC 5 by being directly connected to one of the single board computer's (SBC) USB ports, although the use of a USB hub or wireless USB forwarding device is possible.. The blood pressure monitor module is connected over one of the single board computer's (SBC) 5 internal RS-232 headers and is mounted internally in the chassis of the machine 10. The single board computer (SBC) 5 may be operated with various storage and memory modules attached. This
25 embodiment uses 4 gigabytes of RAM 8 and a 32 gigabyte solid state storage system (SSD) 9 connected using the parallel ATA ports of the single board computer (SBC) 5 although various memory and storage configurations may be used as required by the specific implementation selected. The communications sub-system is a modem 3 connected over RS-232 7, for example a Cinterion MC55i Terminal. Alternatively, a USB module may be used, such as a
30 Huawei E1550 module or equivalent module. The modem 3 is outfitted with a SIM card from a telecommunications service provider.

While the preferred embodiment uses a wireless modem 3, it is alternatively possible to use a fixed line connection with suitable modem or connect to a pre-existing Ethernet wired network.

5 For the software components of the best mode PD machine 10, the single board computer (SBC) 5 runs Windows XP Embedded SP3. The USB scale 2 and blood pressure monitor 1 are interfaced using a manufacturer-specific proprietary communications protocol. Both interfaces are controlled by Visual Basic program built on the .Net platform. Communication with the modem is through the use of a serial terminal to which are issued AT
10 commands, part of the standard Hayes AT command set.

Communication with the server is performed by issuing to the modem AT commands that instructs the modem to send the payload data as an SMS to the gateway modem, which then communicates the information to the server. The present preferred mode of doing so
15 involves the use of the off-the-shelf SMS package that places the received messages into an SQL compatible database by regularly polling the modem. Communication with a primary care provider can be performed directly by sending an SMS, using the AT command language, directly to the primary care provider's mobile phone. This primary care provider may be a nurse or a family member.

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Voice communication may be initiated by the PD machine 10 in an analogous fashion using a modem-specific AT command. The datastream which carries the sound information to and fro may be transmitted over the USB interface which is then channeled to the Windows XP standard audio driver for output, as is the case with the E1550, or over an analog audio cable
25 which is physically connected to an analog audio output on the modem and is connected to a mixer which mixes the other audio output from the single board computer (SBC) 5 with the audio output received from the modem. Audio input is handled in a similar fashion, either over USB or through a physical analog connection to the line or microphone in port of the SBC.

30 Figures 3(a) and 3(b) are screenshots of the display of the PD machine 10 that are displayed in the course of the patient taking measurements. In this embodiment, upon initiation of the PD therapy procedure, the patient places the blood pressure cuff upon their arm and clicks the "Next" button on the PD machine 10 to initiate the blood pressure management. The patient is then required to step on the weight scale 2 that is positioned near the bottom of the

PD machine for the weight measurement to be taken. If the PD machine 10 detects no incoming data or that the incoming data indicates no reading after a predetermined period of time (example 2 minutes), it assumes that the patient has not taken the measurement, a local alert is generated. In the event that the PD machine 10 receives data that is not physiologically possible, it assumes that there has been a peripheral malfunction and begins a machine diagnostic routine. In the event that the PD machine 10 receives data within physiological limits, it proceeds to display the trending graphs and continues with the treatment.

Figure 4 is a flowchart that illustrates the generation of escalating levels of alert. During the course of the PD therapy, if the PD machine 10 detects no incoming data or that the incoming data indicates no reading after a predetermined period of time (for example 30 seconds to 1 minute), it assumes that the patient has not taken the measurement, a local alert is generated. On detection of non-compliance, the PD machine 10 first prompts the patient by generating a local alert as to whether the patient would like to retry the measurement process. If the patient accepts, the measurement process repeats. The patient may have the option to over-ride the alert and proceed with the therapy. In the event that the PD machine 10 receives data that is not physiologically possible, it assumes that there has been a peripheral malfunction and begins a machine diagnostic routine. In the event that the PD machine 10 receives data within physiological limits, it proceeds to display the trending graphs and continues with the treatment. All non-compliance events are logged and stored in the internal database of the PD machine 10 for referral purposes which logs the event and polls its database for the number of consecutive previous non-compliance events.

After a local alert generated to prompt the patient to retry the measurement process, if there is no incoming data or that the incoming data indicates no reading after predetermined period of time, the non-compliance event is logged and stored in the internal database of the PD machine 10. After a predetermined period of time where there is no incoming data or that the incoming data indicates no reading, if the sum of consecutive non-compliance events leading to the present event is one (1) or greater than three (3), the PD machine 10 displays a local alert to prompt the patient to comply with the PD therapy procedure. The non-compliance event and the intervention are then logged and stored in the internal database of the PD machine 10.

In the event that the sum of consecutive non-compliance events leading to the present event is two (2), the PD machine 10 displays an educational video on the monitor display,

informing the patient as to the rationale underlying the need for compliance. The non-compliance event and the intervention are then logged and stored in the internal database of the PD machine 10.

5 In the event that the sum of consecutive non-compliance events leading to the present event is three (3), it initiates a remote alert in the form of SMS communication to the nursing center to notify the nurse who can then call into the voice-modem installed in the PD machine 10. The PD machine 10 will then pick up the call using the appropriate AT command where the nurse can speak to the patient directly. The nurse may attempt to persuade the patient to
10 comply with the PD therapy procedure. The non-compliance event and the intervention are then logged and stored in the internal database of the PD machine 10.

Figure 5 is a flow chart of the process of communicating alerts according to the degree of non-compliance by the patient. When the PD machine 10 detects that no reading has been
15 performed, it checks to see if the patient's non-conformance is a chronic problem or whether it is a relatively rare instance where this is a flag set by the nurse and physician. Chronic non-conformers are unlikely to be influenced by machine-mediated responses and so a reminder is displayed and a notice is sent via the wireless modem to the central server to be recorded in the patient's file, where it will appear in the physician interface. Further action will be at the
20 discretion of the physician with the help of a cognitive behavioral therapist.

Should non-conformance not be chronic, an alert in the form of an SMS is generated to immediately notify the nurse in-charge of the patient, so as to allow immediate intervention. The nurse would then be able to call the voice-modem installed in the PD machine 10 where the
25 nurse can speak to the patient directly.

An alternative embodiment involves the PD machine 10 starting out by showing an educational video to the patient, explaining the necessity of compliance with the monitoring components of the therapy that escalates to direct intervention on the part of the nurse on the
30 second consecutive day of non-compliance. After intervening, the nurse would log the non-compliance event and the intervention in the patient's file, which the nurse would access as a web service.

Another alternative embodiment involves informing the central server of the non-compliance event immediately and having the server executes a nurse selection algorithm prior to informing the selected nurse. Nurse selection algorithms include identifying an on-shift nurse as opposed to a single constant nurse for the patient, demographically matching a nurse out of
5 a pool of available nurses or matching patient preferences with available nurses.

An optional component of the system may also signal family members or other non-medical persons to provide on-site assistance to reinforce compliance behaviors. Signaling is preferably by way of SMS to the recipient's mobile device. The assistance may include
10 speaking to the patient personally but may also involve physically assisting the patient so as to reinforce in muscle memory of the physical actions required.

Figure 6 is a flow diagram that illustrates communication to and from the PD machine
10. Communication between the PD machine and a primary care provider is performed directly
15 by sending an SMS, using the AT command language, directly to the primary care provider's mobile phone. This primary care provider may be a nurse or a family member.

Communication between the web server and the nurse in a nursing center is performed where the nurse can retrieve the patient's data obtained from the PD machine 10 which is
20 stored in the web server. Based on the patient's data, the nurse would then be able to use the data as reference and call the voice-modem installed in the PD machine where the nurse can speak to the patient directly.

Communication between the physician in the physician's office and the web server
25 allows two-way communication, whereby a physician may retrieve information the patient's summary, treatment prescriptions and patient's status stored in the web server. Alternatively, the physician may dial-up the PD machine 10 to retrieve and view the latest recorded patient data. In this way, the physician can check and assess the patient's progress and condition at any time. The communication module allows the remote sending of instructions to the patient on
30 how to correct or modify their treatment. For example, the PD machine 10 may present text or other forms of instruction messages on the display monitor of the PD machine 10, in response to commands received from a remote source via the communication module.

The invention may also be embodied in many ways other than those specifically described herein, without departing from the scope thereof.

CLAIMS

1. A peritoneal dialysis (PD) machine (10) comprising:
a blood pressure monitor (1);
5 a weight scale (2);
means for recording in the machine, measurements of a patient's blood pressure and weight taken using the blood pressure monitor and scale;
means for monitoring the frequency with which such measurements are recorded; and
means for generating a local and/or remote alert when the frequency of recording the
10 measurements does not comply with a predetermined schedule.
2. A peritoneal dialysis (PD) machine (10) according to Claim 1, wherein an event is logged in the PD machine each time the frequency of recording the measurements does not comply with a predetermined schedule.
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3. A peritoneal dialysis (PD) machine (10) according to Claim 1, wherein the PD machine is adapted to maintain a count of the number of consecutive non-compliance events.
4. A peritoneal dialysis (PD) machine (10) according to Claim 3, wherein the type of alert
20 generated is dependent upon the value of said count.
5. A peritoneal dialysis (PD) machine (10) according to Claim 3 or Claim 4, wherein the count is resettable manually.
- 25 6. A peritoneal dialysis (PD) machine (10) according to any one of Claims 1 to 5, further comprising a communication module for transmitting a said remote alert.
7. A peritoneal dialysis (PD) machine (10) according to Claim 6, wherein the communication module is wireless.
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8. A peritoneal dialysis (PD) machine (10) according to Claim 7, wherein the wireless communication module uses a cellular network.

9. A peritoneal dialysis (PD) machine (10) according to any one of Claims 6 to 8, wherein the communication module automatically transmits a said remote alert or event to a server or mobile terminal device.

5 10. A peritoneal dialysis (PD) machine (10) according to any one of Claims 6 to 9, wherein the communication module allows for communication between the patient and a medical personnel.

10 11. A peritoneal dialysis (PD) machine (10) according to Claim 10, wherein the said communication is through text-based messages and instructions that are displayable on a monitor display of the machine.

15 12. A peritoneal dialysis (PD) machine (10) according to Claim 10, or Claim 11 wherein said communication module comprises a voice modem which allows the medical personnel to communicate verbally with the patient.

20 13. A peritoneal dialysis (PD) machine (10) according to any one of the preceding claims, wherein visual information is generated on a monitor display of the PD machine to inform the patient of the non-compliance.

14. A peritoneal dialysis (PD) machine (10) according to Claim 13, wherein the visual information includes an educational video presentation.