(57) Abstract: A valve with a smart handle including a memory module to log relevant data. A sensor on the handle determines when the valve is open, and this triggers the start of timers and recording of the "open" event in a log in the memory module. When the valve is closed, the sensor triggers stopping of the timers and recording of the "closed" event in the log. The timer information is used to calculate the duration of the time "open" event, and this, together with the actual data and time of the opening and closing of the valve are recorded in the log. Other relevant information, such as cylinder fill date, cylinder i.d. number, batch number, and patient name or account number may also be logged in the memory module. The log of the events and the corresponding dates and times may be used to prepare invoices for billing gas treatments, for inventory control, and for other record-keeping and control functions.
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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VALVE WITH SMART HANDLE

BACKGROUND OF THE INVENTION:

The present invention relates to valves and, in particular, to a valve with a special handle that tracks the usage of the valve to enable logging and billing. The valve handle may thus be used not only to dispense a gas but, in combination with the disclosed procedure, to provide a method for conveniently providing tracking of the use of the gas and subsequent billing for medical treatments using the gas.

Some medical treatments involve the use of gases that are inhaled by the patient. In the past, medical gas suppliers have charged for the gas in the cylinder at the time of delivering the filled cylinder to the user. This method has been used both for industrial and medical uses. Pharmaceutical gases, dispensed by prescription, have great variability of use from patient to patient due to treatment regimen and dispensing methods. A method of charging for treatment time would be a desirable way for allocating the true value of the product. However, in the past, there has not been a way to automatically track the duration of treatments by cylinder or to tie the treatments to the patients who receive the treatments in order to make it easy to bill for use of the gas.

SUMMARY OF THE INVENTION:

The present invention provides a valve with a smart handle for the gas bottle (or cylinder). This valve records all the treatment information and makes the information readily accessible for use in tracking and invoicing. It permits the vendor to invoice the user for total treatment time and to provide users, such as hospitals or clinics, the information to bill individual patients. It also provides both the vendor and the user with data which is useful for trend analysis and inventory control.

The valve handle includes sensors for sensing the opening and closing of the valve, a timer for timing the duration over which the valve is opened, and an electronic memory device which records the pertinent information. The information recorded by the memory device may include the cylinder fill date, the lot batch number, cylinder number, the patient’s name, the number of times the valve is
opened, and the date, time, and duration of each opening of the valve, as well as additional information, if desired.

The data then can be readily transferred from the memory device to a device that generates reports or bills.

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BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is an exploded, perspective view of an example of a valve with a smart handle made in accordance with the present invention;

Figure 1A is the same view as Figure 1 but from a different perspective and with the lock mechanism further exploded from the view;

Figure 2 is the same view as Figure 1 but from a different perspective;

Figure 2A is the same view as Figure 1 but with the lock mechanism further exploded from the view;

Figure 2B is a schematic diagram showing the processor mounted on the handle of Figure 1 and the input/output devices associated with it;

Figure 3 is a side view of the valve of Figure 1 mounted on a gas cylinder;

Figure 4 is an enlarged plan view of the valve and cylinder of Figure 3;

Figure 5 is an exploded, perspective view of the handle part of the valve of Figure 1;

Figure 6 is an enlarged bottom view of the assembled handle of Figure 5;

Figure 7 is an enlarged side view of the assembled handle of Figure 5;

Figure 8 is a section view taken along the line 8-8 of Figure 7;

Figure 9 is a schematic operational logic diagram for the valve handle of Figure 1;

Figure 10 is a perspective view of the handle of the valve of Figure 1;

Figure 11 is a perspective view of a hand-held recorder used to export data from the valve of Figure 1;

Figure 12 is a perspective view of a button-type storage device used with the recorder of Figure 11;

Figure 13 is a hand-held portable computer which may be used to initialize the memory device on the valve of Figure 1, and which may be used to export data from the memory device;
Figure 14 is a wand reader used to transfer data to and from the valve handle of Figure 1 and to and from a computer;

Figure 15 is a perspective view of a BlueDot receptor that may be used for transferring data from a button-type memory module (as shown in Figure 12) to a computer; and

Figure 16 is an adapter which can be used to download data from the valve of Figure 1 to a button-type memory module.

DESCRIPTION OF THE PREFERRED EMBODIMENT:

Figures 1-16 show a first preferred embodiment of the present invention. A valve 10 is provided, which may be attached onto a gas cylinder 12. The cylinder may contain pharmaceutical gas or other gases.

Referring to Figures 1, 2, and 3, the valve 10 includes a valve body 14, a stem 15 projecting upwardly from the valve body 14, and a handle 16 mounted on top of the valve stem 15 for manually opening and closing the valve 10. Figures 1 and 2 show that the valve body 14 includes a threaded inlet port 18 which screws onto the outlet port of the cylinder 12. The valve body 14 also includes an outlet port 20. The valve body 14, the outlet port 20, and the inlet port 18 may be modified for specific uses, cylinder sizes, or gases.

The handle 16 mounts on the valve stem 15. An operator grasps the handle 16 and rotates it in order to open and close the flow of gas from the cylinder 12 to a ventilator or other gas dispensing device (not shown). The handle 16 has a substantially circular cross-section and includes ribs around its outer edge to facilitate grasping the handle.

As shown in Figure 2B, several electronic devices are mounted in the handle, including a processor 23, a timer 21, a reset button 27, an open/closed sensor 28, a battery 25, a display 26, and an electronic memory device 22. In this embodiment, the memory device 22 communicates with a one-wire port 22' that projects to the exterior of the handle 16. The one-wire port 22' in this embodiment is a metal can, which has the same shape as the portable memory buttons 22A, shown in Figure 12, that can be used to transfer data from the handle’s memory 22 to other devices.
This enables the same communication devices to be used with the port 22 and with the memory buttons 22A.

Most of the components of Figure 2B are housed inside a compartment formed by the handle 16 and the cover 24 in this preferred embodiment. The processor 23 is located inside the handle cover 24 and communicates with the electronic memory device 22. Also inside the handle cover 24 are two (2) small batteries 25. While Figure 2B shows a single timer 21, there preferably are at least two timers 21, one of which is a calendar, and the other of which is an event timer. The reset button 27, located inside the handle 16, may be depressed to reset the event timer 21. At least a portion of the top surface of the handle cover 24 is clear, in order to permit the user to view the LCD display 26 mounted inside the handle 16.

On the underside of the handle 16 is mounted the sensor 28, as seen in Figures 1A, 2 and 8. The sensor 28 that is used in this preferred embodiment is a proximity switch model MK20-BV50170 manufactured by Meder Inc. A collar 30 is mounted onto the valve body 14, just below the handle 16. This collar 30 holds a stationary magnet 32 (See Figure 1). In the embodiment shown here, the collar 30 has a twenty-four-sided interior cross section 34 which fits directly onto the nut 36 on the valve body 14, so the collar 30 remains stationary relative to the valve body as the handle 16 is rotated to rotate the valve stem 15, in order to open and close the valve. The angular position of the collar 30 may be changed by lifting it up and rotating it, then fitting it back down over the nut 36. However, this can be done only when the handle 16 is removed from the valve 10.

The handle 16 is protected from undesired removal by a special stud 38 (such as a "Torx" stud) and its corresponding security nut 39 (See Fig. 5), making it difficult for anyone to tamper with the position of the collar 30 and magnet 32, as will be explained in detail later. The proximity sensor 28 is mounted on the handle 16, and the collar 30 is positioned so that, when the handle 16 is rotated to the closed position, the sensor 28 is adjacent to the magnet 32 that is fixed to the collar 30. When the proximity sensor 28 is adjacent to the magnet 32, it sends no signal to the processor 23, thereby indicating that the valve is in the "closed" position. When the handle 16 is rotated to open the valve, the proximity sensor 28 senses that it has been moved away from the magnet and sends a signal to the processor 23,
indicating an “open” position. The processor 23 instructs the memory 22 to record the event of opening the valve and to record the time and date of the event as indicated by the calendar timer 21. The processor 23 instructs the memory device 22 to continue checking the position of the valve as long as the valve 10 is open.

When the valve is closed, the processor uses the logged open and close times to calculate the amount of time the valve was open and instructs the memory device 22 to record that duration as well a recording an accumulated open time duration. Thus, every time the valve 10 is opened, the time and date of the event is recorded, the closing time and date is recorded, the duration of time during which the valve 10 is open is calculated and logged, and the accumulated open time is calculated and logged. Figure 9 shows the operational logic for the timing and logging operation.

While the simple proximity sensor 28 and magnet 32 are used in this preferred embodiment, many other arrangements are known in the art for sensing and signaling when the valve 10 is open and when it is closed, and it would be obvious to those skilled in the art to use other known sensing arrangements.

The display 26 may be arranged to display in a variety of ways. However, in this embodiment, it alternates flashing of two different numbers – first the accumulated open time, and then the open time for the current event preceded by a “plus sign”. If the valve is closed, then the current event open time flashes as a “minus sign” with no digits adjacent to the “minus sign”.

The threaded security stud 38 is fixed at its top end to the handle cover 24 and projects downwardly. It is received by the special security nut 39, which is rotatable relative to the handle 16 but is trapped onto the underside of the handle 16. The nut 39 must be unthreaded from the stud 38 in order to remove the handle cover 24 to allow access to the interior of the handle 16. This arrangement helps make the handle 16 tamper-proof. Once the handle cover 24 has been removed, there is access to the batteries 25, reset button 27, and so forth, and there is access to the screw 37 which secures the handle 16 to the valve stem 15.

An optional locking device 54 (See Figures 1A and 2A) prevents inadvertent rotation of the handle 16 during transport and can only be installed when the valve handle 16 is in the closed position. This serves to provide additional visual cues of the valve handle 16 position to the user. The locking device 54 preferably is made
of plastic and includes a curved wall 56, which conforms closely to the shape of the outside wall of the valve handle 16. An arm 58 extends inwardly from the lower end of the wall 56, and a finger 60 projects upwardly from the free end of the arm 56. The finger 60 is designed to mate with the hole of the security nut 39, while the arm 58 fits snugly within the notch 40 of the fixed collar 30. A tab 62 at the top end of the locking device 56 projects both outwardly and inwardly, so that, when installed, the inward portion of the tab 62 snaps over the top of the handle 16 to retain the locking device 56 in place on the handle 16, with the finger 60 mated to the security nut 39 and the arm 58 in the notch 40 of the collar 30.

Since the collar 30 is fixed on the valve 14, and the arm 58 of the locking device 54 is caught in the notch 40 of the collar 30, the locking device 54 is fixed and does not rotate relative to the valve body 14. Furthermore, since the finger 60 is attached to the arm 58 (which is part of the locking device 54), and is mated to the security nut 39 (which is part of the handle 16), then the handle 16 is also unable to rotate relative to the valve body 14. In order to open the valve 10, the locking device 54 is removed by pushing downwardly on the outwardly-projecting portion of the tab 62 to release the inwardly-projecting portion of the tab 62 from the top of the handle 16, and then the locking device 54 is slid downwardly to remove the finger 60 from the nut 39 and to remove the arm 58 from the notch 40. Then, the handle 16 can be rotated to open the valve 10. As long as the locking device 54 is properly attached to the valve 10, accidental opening of the valve 10 (such as due to vibration during transport) is unlikely.

Installation of the valve and handle:

The following steps may be taken to install the valve and handle on the gas cylinder. First, the valve body 14 (without the valve handle 16) is installed onto the cylinder 12 by threading the inlet port 18 of the valve body onto the cylinder 12. At this point, the valve stem 15 is in the full clockwise (closed) position. The cover 24 is removed from the handle 16, and the handle 16 is temporarily placed onto the valve stem 15 by placing the square hole 15A of the handle 16 over the valve stem 15. The handle 16 should be in a position in which there will be easy access to the
memory module 22. The location of the security nut 39 should be noted, and then the handle 16 should be removed from the valve stem 15.

As shown in Figures 2 and 6, the collar 30 has a notch 40, which should only line up with the security nut 39 when the valve handle 16 is in the closed position, so the only time there will be access to the security nut 39 will be when the valve is closed. This will ensure that the handle 16 may only be removed when the valve 10 is closed. The target collar 30 should be installed over the nut 36 with the notch 40 in the proper position to provide access to the security nut 39 when the valve is closed. The position of the notch 40 may be adjusted by lifting the collar 30 off of the nut 36, rotating the collar 30, and then reinstalling the collar 30 on the nut 36 until the notch 40 on the collar 30 matches up with the intended location of the security nut 39. The 24-point cross-section 34 of the collar 30 allows for precise positioning of the collar 30 on the hexagonal nut 36.

Once the collar 30 and its notch 40 and magnet 32 are properly positioned onto the valve body 14, the handle 16 can then be placed back onto the valve stem 15, with the square opening 15A of the handle 16 fitting onto the valve stem 15, making sure to align the security nut 39 with the notch 40 on the collar 30. The handle 16 is then secured to the stem 15 by using a Fender washer 35 and threading a button-head cap screw 37 from the top side of the handle 16 into the threaded top of the stem 15, as is well known in the art. (See Fig. 1)

The reset button 27 on the inside of the handle 16 is then depressed to reset the timers 21. The handle cover 24 is then installed onto the handle 16 by lining up the security stud 38 with the security nut 39 and tightening the security nut 39 from below, extending a tool upwardly through the notch 40. This draws the handle cover 24 onto the handle 16. The LCD display 26 should read -00.0. The minus sign indicates that the valve handle is not currently logging time and ensures that the magnet 32 on the target collar 30 and the sensor 28 on the handle 16 are properly aligned. When the valve handle 16 is in the closed position, the LCD display 26 toggles between a “----” display indicating that the valve 10 is closed, to a “-XXX” display where XXX represents the total accumulated time the cylinder has been open. When the valve handle 16 is in the open position, the LCD display 26 toggles between the treatment time display and the total accumulated time display.
Configuring the valve with smart handle

Once the valve handle 16 is reset and is mounted on the cylinder 12, the valve handle should now be configured to input the initial parameters such as:
- Born on date (date when cylinder was filled)
- Cylinder serial number
- Gas lot number
- Set the timers (which may include a calendar timer and an event timer)
- Clear the log registers
- Additional area may be available for recording specific notes or information relative to a specific treatment or lot.

This initial configuration would typically be done by the distributor who is filling and supplying the filled cylinders to the user. The distributor uses a computer in which the required software has been previously installed and the initialization parameters have been previously inputted. The distributor inputs the initialization parameters from its computer to the smart handle 16 by some known data transfer mechanism. In this preferred embodiment, the distributor uses the transfer device 44 shown in Figure 14. This transfer device plugs into the distributor's computer at one end, and the other end fits onto the one-wire port 22' on the handle 16 to transfer the initialization parameter data from the distributor's computer to the memory 22 in the valve handle 16.

Similarly, the user (such as the hospital) may add more data into the memory device 22 of the valve 10. This information may include a patient identification number, a treatment number, and so forth, which the hospital may use for its record keeping and for billing its patients or other end users. One way to add that data is by using a hand held computer 50 or laptop (not shown), inputting the information into the computer 50 and transferring that information to the memory device 22 through an adapter 48 (shown in Figure 16) and through the transfer device 44.

The hospital or other user, as well as the distributor, may later download the data from the memory device 22 to be used for record keeping and billing.
Valve operation

Typically, the outlet port 20 of the valve 10 is connected to a delivery device, such as a ventilator (not shown), which is used to adjust the concentration and flow rate or to mix gases administered to the patient. When the valve handle 16 is turned to open or close the valve, the proximity sensor 28 triggers the processor 23 to instruct the memory device 22 to log the event, including date, time, and whether the event was an opening or a closing of the valve. This information is stored in a non-volatile, read-only-memory (NVROM) in the memory device 22. As was explained above, Figure 9 shows a schematic operational logic diagram for the timer of the valve 10. Thus, as the handle 16 is rotated to open the valve 10 in order to provide gas treatments to patients, the memory device 22 in the handle 16 records the number and duration of the treatments.

All this information may be read or downloaded by the user and/or by the supplier, using a number of data transfer methods. Three methods are described here, but others may also be used.

1. Using a PIR-2 reader (See Figure 11), the information may be downloaded into portable DS-1996 iButtons 22A (See Figure 12). Each portable iButton 22A has enough memory to store the data for 12 valves, with each valve having up to 72 logs.

The data on the portable iButtons 22A may then be transferred to a computer via a DS-1402 BlueDot receptor 52 (See Figure 15). The data may be imported into a suitable software program, such as a spread sheet program, to generate usage reports or billing reports.

2. The data may be downloaded directly onto a hand-held or lap-top computer 50 using a wand reader 44, as shown in Figure 14, which communicates through the one-wire port 22', and then it may be downloaded from the portable computer 50 to a main computer. Depending upon the types of ports on the computer, an adapter 48, as shown in Figure 16 may be used. Again, the data may be imported into a suitable software program to generate usage reports or billing reports.
3- The data may be sent directly from the port 22' on the handle 16 to a printer.

The user may use the generated reports to keep a record of the treatments on the patients, for record keeping, for billing the patients, and for checking the billing it receives from its supplier. The supplier may use the generated reports or print outs to bill the user for the treatments and for inventory control purposes.

For instance, a worker may walk around the user’s facility (a hospital or clinic, for example) at certain intervals with a reading device and download the data from the ports 22' on the handles 16 of the cylinders 12 to a portable iButton 22A or to some other portable recording device. It would also be possible for the handle 16 to include a transmitter to transmit the data to a remote recording device at intervals or on command, as desired. The HA7MB reader of Figure 16 (produced by Point Six, Inc. of 391 Codell Dr., Lexington, Kentucky 40509, USA) may be used to transfer data from the memory device 22 to portable iButtons 22A using a handheld computer 50. The collected data on the iButtons 22A is then downloaded into a main computer. The software in the computer then uses the data that has been collected to generate reports, to track treatments, do billings, and to control inventory. While this method of moving data from the valve handle 16 to the computer station is preferred, it is understood that many other methods for transmitting the data from the valve 10 to the main computer could be used.

In the first preferred embodiment shown in Figures 1-16, a Dallas Semiconductor 1-wire protocol establishes a method for storing and retrieving information from the handle.

Some advantages of this Smart Valve handle system include:

- The system provides a convenient way to track and charge for therapy, as the gas is being used, instead of just charging for a bottle of gas. This may be much more desirable for the parties.

- Actual treatment time can be ascertained directly at the gas cylinder, and the smart valve 10 is relatively tamper proof, so there is little opportunity for error or fraud.

- Little or no paperwork is required, as all the data is stored in electronic format.
- The data may be stored as a comma delimited file, making it easy to import the data into spreadsheet or database software (such as Access™ or Excel™) for data servicing and manipulation.

- Data logs are also maintained in the Smart Handle device allowing for a back-up of the downloaded material.

- The record of the Born On Date (date the cylinder is filled) and Batch number reside at the bottle in the memory device 22. It is not necessary to search this data in files from a serial number or bar code.

- The system allows for expansion and software development which will provide hospitals and researchers the ability to track trends in patient use of various treatments, develop therapy protocols, assign patient ID to cylinders, identify and control cylinders for blinded clinical trials, and other uses currently handled by means of complicated and labor-intensive administrative methods.

- Various password protections may be used to ensure that only the appropriate users can make certain inputs of data. For example, only the enterprise filling the cylinders should be able to input the Born On Date.

The embodiment described above is only intended to be one example of a device made in accordance with the present invention. It will be obvious to those skilled in the art that modifications may be made to the preferred embodiment described above without departing from the scope of the present invention.
What is claimed is:

1. A valve handle for mounting on a valve stem to open and close a valve, comprising:
   a valve handle body, defining a receptacle for receiving the valve stem;
   a sensor on said valve handle body, for sensing the opening and closing of the valve;
   a timer on said valve handle body; and
   an electronic storage device mounted on said valve handle body, in communication with said sensor and said timer, wherein said storage device records the date and time of opening and closing of the valve and the duration of time that said valve is open.

2. A valve handle for mounting on a valve stem to open and close a valve as recited in claim 1, wherein said timer includes a calendar timer and an event timer.

3. A valve handle for mounting on a valve stem to open and close a valve as recited in claim 2, and further comprising an electronic data input means in communication with said storage device, for permitting a user to enter additional data to be stored with said date and time.

4. A valve handle for mounting on a valve stem to open and close a valve as recited in claim 1, wherein said sensor includes a proximity switch.

5. A valve handle for mounting on a valve stem to open and close a valve as recited in claim 4, and further comprising data output means for downloading data from said electronic storage device.

6. A valve with a smart handle, comprising:
a valve body for controlling the dispensing of fluid through said valve;

a valve stem projecting from said valve body;

a valve handle mounted on said valve stem for opening and closing said valve;

a sensor on said valve handle, which senses the opening and closing of said valve;

timer on said valve handle; and

electronic storage device mounted on said valve handle, in communication with said sensor and said timer, wherein said storage device records the opening and closing of said valve and the time of said opening and closing events.

7. A valve with a smart handle as recited in claim 6, and further comprising a port in communication with said storage device, permitting a user to enter additional data to be stored by said electronic storage device.

8. A valve with a smart handle as recited in claim 6, wherein said sensor includes a proximity switch.

9. A valve with a smart handle as recited in claim 8, and further comprising a target collar mounted on said valve body, said collar including a magnet which triggers said proximity switch.

10. A valve with a smart handle as recited in claim 9, wherein said target collar defines a notch to allow access into said valve handle only when said valve is in a closed position.

11. A valve with a smart handle as recited in claim 10, and further comprising a handle cover and a fastener which secures said handle cover onto said handle, wherein access to said fastener is through said notch.
12. A valve with a smart handle as recited in claim 11, and further comprising data output means for downloading data from said electronic storage device.

13. A valve with a smart handle as recited in claim 12, and further comprising a locking device which prevents relative motion of said handle relative to said collar.

14. A valve with a smart handle as recited in claim 13, wherein said locking device includes an arm which engages said notch in said target collar, and a projection which engages said handle.

15. A method for tracking the use of gas for medical treatments, comprising the steps of:

   moving a handle to open a valve;

   sensing the opening of said valve;

   electronically recording onto a memory device as data the opening of the valve and the time the valve was opened;

   moving said handle to close said valve;

   sensing the closing of said valve by a sensing means, and electronically recording onto a memory device as data the closing of the valve and the time the valve was closed;

   calculating from said times a duration of time that said valve was open and electronically recording that duration as data.

16. A method for tracking the use of gas for medical treatments as recited in claim 15, wherein the sensing means and the recording device are located on the handle.
17. A method for tracking the use of gas for medical treatments as recited in claim 16, and further comprising the step of:

   inputting and recording onto the memory device patient identification information.

18. A method for tracking the use of gas for medical treatments as recited in claim 17, and further comprising the steps of:

   importing said recorded data and patient identification information from said memory device into a computer; and using said imported data to create a billing invoice.
Fig 28
HA7MB - Palm IIIxe, VII to 1-Wire Host Adapter with iButton site.

**FIG 16**