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A prototype device to measure and supervise urine output of critical patients

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1. Introduction

Patient monitoring history can be considered to have started in 1887, when the British Augustus D. Waller made the first electrocardiogram (ECG) recording on a human being (Waller, 1887). The first commercial monitoring device was invented by the Nobel Prize winner, Willem Einthoven, who in 1903 embarked on negotiations with the Cambridge Scientific Instruments Company to commercialise his “string galvanometer” for recording electrocardiograms (Einthoven, 1903). Since then, commercial monitoring devices capable of recording and supervising the status of many other physiological parameters have been developed: heart rate, respiratory rate, systolic, diastolic and mean blood pressures, blood levels of oxygen saturation, brain waves, intracranial pressure, partial pressure of expired oxygen, nitrogen and carbon dioxide -just to mention a few.

However, at present there is a very relevant physiological parameter that is still measured and supervised manually by critical care unit staff: urine output. This parameter is the best indicator of the state of the patient's kidneys. If a kidney is producing an adequate amount of urine it means that it is well perfused and oxygenated. Otherwise, it indicates that the patient is suffering from some pathology. When the urine output of a patient is too low the patient is said to have oliguria. If the patient does not produce urine at all, then he/she is said to have anuria. Sometimes, the urine output can be too high; in these cases the patient is said to have polyuria.

Urine output is also essential for calculating the patient's water balance; and is used in multiple therapy protocols to assess the reaction of the patient to the treatment. Two of the more prominent clinical algorithms where urine output plays a central role are the resuscitation of septic shock patients (Rivers, 2001), and the resuscitation and early management of burn patients (Mitra, 2006). In the latter patients, where endovenous resuscitation is required, a Foley catheter is placed very early in the treatment process in

order to monitor urine output. While the end points of the resuscitation are debatable, hourly urine output is a well-established parameter in the fluid management of these patients, as well as one of the most reliable assessments of the patient's state and evolution. In the case of the septic shock patient resuscitation, achieving a certain minimum value for the urine output itself is a therapeutic target.

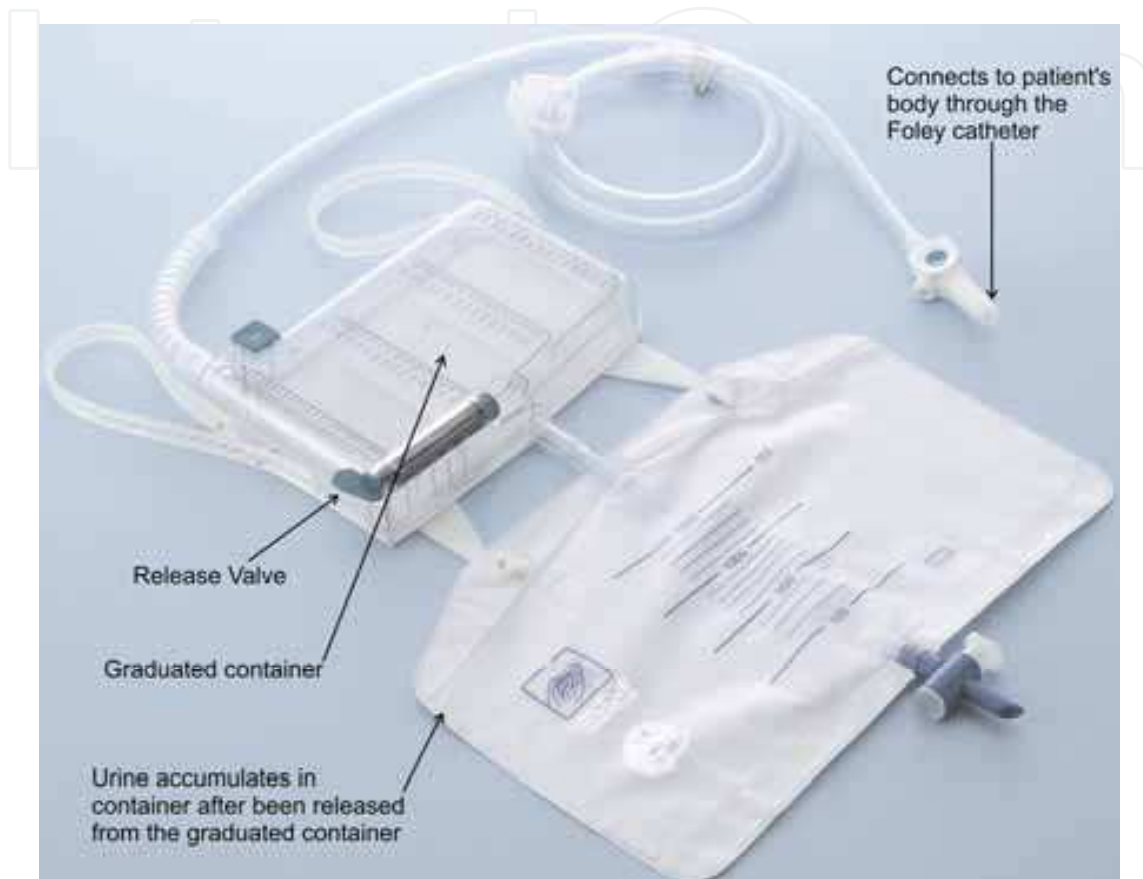


Fig. 1. Commercial urine meter

At present, critical patients' urine is collected in a graduated container (see Fig. 1). Every hour, the nursing staff manually records the reading of the container of every patient, and operates a valve which releases the urine into a larger container. In critical care units, this procedure must be performed 24 times a day, 365 days a year. As any repetitive and monotonous task, this one is prone to errors. A device capable of automatically measuring the patients' urine output, and supervising the attainment of the established therapeutic goals, would release the healthcare staff from a considerable amount of work, and would permit measurements to be carried out more frequently.

This paper presents a device capable of recording and supervising the urine output of critically ill patients. Section 2 describes this device. Section 2.1 presents a sensor specifically designed for this purpose upon which the device is based. Section 2.2 describes the operation of a microcontroller that takes the sensor readings and sends them via Bluetooth to a PC. The microcontroller also controls the operation of an actuator that releases the urine contained in the sensor into a larger container. The actuator is presented in section 2.3. Through a program installed in a PC, the healthcare staff can inspect the production of urine

during the patient's stay in the critical care unit, and set therapeutic goals for this parameter. These goals are automatically supervised; if they are not met, the PC triggers an auditory warning. Section 2.4 describes this software. The device has been successfully validated (using water) by operating it continuously for four consecutive days. The results of this validation are shown in Section 3. Section 4 discusses the results of this work, and Section 5 contains a series of conclusions and lines of future extension.

2. Device design

One of our design goals was to create a device that could be competitive in cost with the manual urine meters currently employed. Due to the higher complexity of our system, that will require sensors, actuators and microcontrollers, it will not be feasible to reach a price similar to the commercial urine meters -around five euros. However, it may be feasible to design a device whose disposable parts -all those which come into contact with the urine- have a low cost, although the price of non-disposable parts is higher. The latter parts can be amortized over a longer period of time; hence its economic impact on the overall price of the device can be negligible.

This goal, along with that of obtaining a robust and simple to operate device, were the main factors that guided the design process.

2.1 The sensor

In the design of the sensor used to measure the urine output a large number of constraints must be taken into account. On the one hand, any component of the device that is in contact, or may enter in contact, with the urine of the patient cannot be reused for different patients. Furthermore, the current commercial devices are usually changed approximately every week for hygienic reasons. Therefore, any component of the device that is or may be in contact with the urine must be easy to dispose of, and should have a low price. Being in contact with urine also means that the component is in indirect contact with the patient's body through the Foley catheter -the flexible tube that is passed through the urethra into the bladder during urinary catheterization to drain urine. Therefore, the component has to be sterilized before it is used. Sterilization of sophisticated sensors that have a lot of parts, possibly encapsulated in some type of covering, can be complicated.

The urine usually is acidic, although sometimes it can be slightly basic -its pH varies between 4.5 and 8. It contains Uric acid (between 25-75 mg/l), Urea (between 15-34g/24h), Sodium (between 130-260 mEq/24h), Potassium (less than 90 mEq/24h), Chlorine (between 110-250 mEq/24h), and Copper (less than 30 mcg/24h), among other components (Brunzel, 2004). Thus, it can be quite corrosive, especially for metals.

Finally, the device must allow the system to provide feedback on the fulfillment of the therapeutic goals for the urine output at least every hour, in order to be able to provide similar information to that produced manually by the nursing staff. In some cases, these therapeutic goals may be as low as 0.5 milliliters of urine per hour per kilogram of the patient's weight. For a 60 kg patient, this means that the sensor must be capable of providing reliable measurements of at least 30 ml of urine, although it would be desirable to be able to measure smaller quantities.

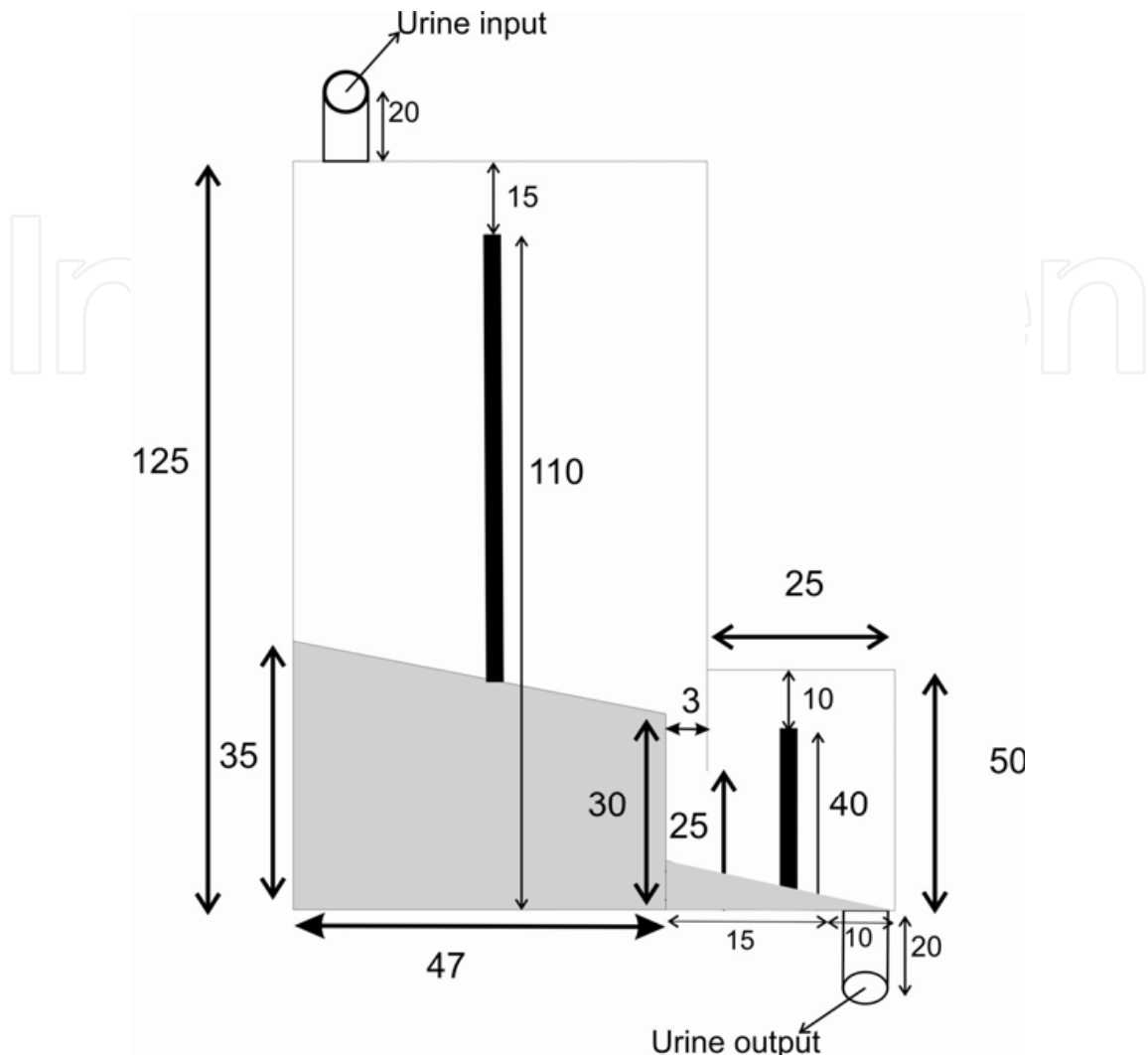


Fig. 3. Lateral view of the sensor. All sizes are shown in millimeters. Floats and the metal contacts have been excluded from the drawing. Gray areas correspond to solid regions.

We finally opted for building a sensor specifically designed for this problem. The sensor is based on a float which moves vertically along a pole and has a metallic surface on top. Urine makes the float rise along the pole until the metallic surface reaches two metal contacts placed at the top of the container, indicating that the container is full (see Fig. 2). This simple design has a flaw: the container must have a volume small enough to monitor the urine output of a patient who may have oliguria. This may be as small as 30 ml per hour. Thus, the container must have a maximum volume of 30 ml to be able to identify the oliguria state in less than an hour for an adult patient.

However, if the patient were producing normal amounts of urine or, even worse, if he/she has polyuria -these patients may produce up to 1 litre of urine per hour- a container of such a low volume would require its content to be released up to several hundred times per day. Our intention is to incorporate an actuator that automatically releases the urine to a container of larger volume, similar to the way the nursing staff manually releases the urine into a larger container every hour. The fact of carrying out several hundred valve operations per day can cause a considerable stress both in the valve and on the actuator. The result

would be an increase in price of an actuator and valve capable of supporting several thousand openings during its lifetime without breaking the sterility of all tubes and containers that come into contact with urine and, therefore, are in indirect contact with the patient's body.

To resolve this problem, we designed a sensor with two different volume containers, each one of them equipped with a float similar to that we described above (see Figs. 2 and 3). The smaller container has a volume of 15 ml, permitting an oliguria warning to be triggered for a 60 kg patient in half an hour. This is half of the time that would be required to detect this problem from the measures taken manually by the nursing staff. For a patient of average weight, who does not have oliguria or anuria, the container should be filled in less than 20 minutes.

The purpose of the smaller container is to provide an early warning of low urine output. If the patient has oliguria, a precise and continuous monitoring of the urine output is needed. Thus, if the small container does not fill in the expected time, when it gets full it will be emptied, and we shall measure again the time required to fill it. Since the patient is producing a very small amount of urine, the small container will be filled between 10 to 30 times a day; therefore, the actuator will not be subjected to significant stress.

The sum of the volumes of both containers is approximately 180 milliliters. If the patient produces normal amounts of urine, or if he/she has polyuria, when the small container gets full, its content will not be released, and the larger container will start to fill. Therefore, for a patient who produces 5 liters per day, the actuator will be triggered about 25 times a day.

In order to operate correctly, this sensor must be built in such a way that the urine does not begin to accumulate in the large container until it has completely filled the small one. This was achieved by making the bottom of the large container solid (see the grey area of Fig. 3) and inclined towards the small container. The bottom of the small container is also inclined towards an exit tube placed on the right part of the bottom of the small container (see Fig. 3), to facilitate the emptying of both containers.

The fact that the small container is at a lower level than the big one can cause the metallic contacts of the small container, and the top metal surface of the container's float, to be under the urine when the large container begins to fill. As we have already indicated, the urine can be quite corrosive for metals. The first sensor design showed that, after 48-72 hours of immersion in a saline solution with similar properties to urine, the metal oxide accumulated on the metal parts -which were made of copper and aluminum- caused the sensor to malfunction, since it was not always able to detect the filling of the small container.

To address this problem, the small container was designed in such way that when it gets full the top has an empty space 15 mm in height. This space is enough to prevent both the metal contacts and the top of the float from coming into contact with the urine.

The sensor described here was designed using the software Pro/Engineer Wildfire, and was built using a rapid prototyping printer -Prodigy Plus- manufactured by Stratasys (Stratasys, 2009). This printer builds components through the deposition of successive layers of molten material and is accurate to a few tenths of a millimeter in the measures of the components it builds. The entire structure of the sensor was built with this printer; only the floats and the metal contacts had to be added to complete it.

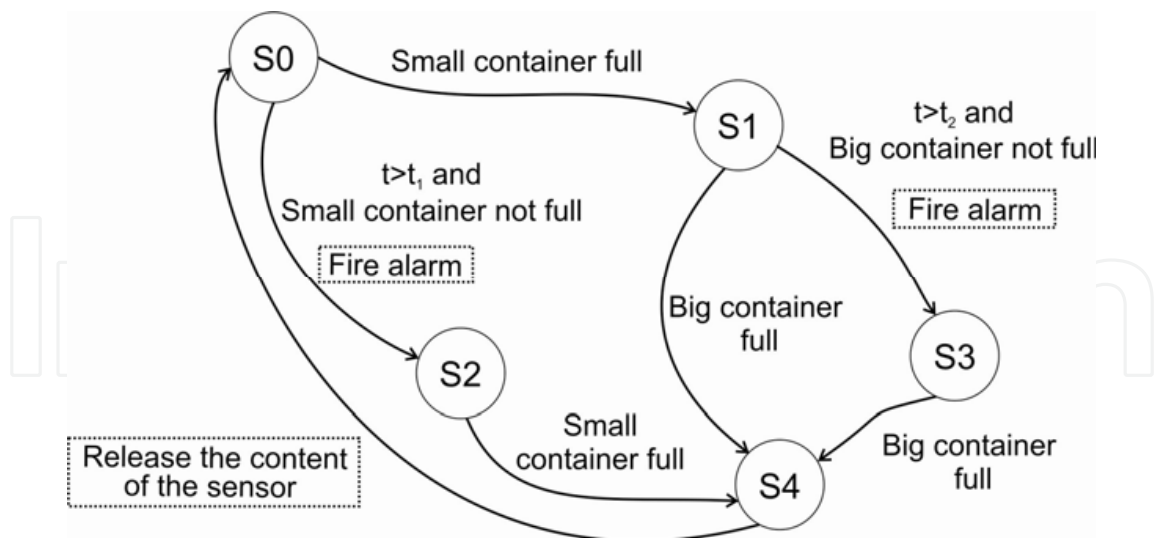


Fig. 4. Finite state machine describing the operation of the micro controller. The conditions of the transitions are shown on each arc, and the actions taking place in each transition are indicated by text surrounded by a dotted line.

2.2 Actuator design

One of our goals is to provide more frequent measurements of urine output. This has led us to design a container-sensor with low volume -15 ml for the small container, and 180 for the overall sensor. The container currently used to take manual measurements usually has volume of 500 ml. The use of a smaller volume container makes it necessary to release its content more frequently.

Another of our goals is to alleviate the workload of healthcare staff by automating as much as possible all the tasks related to monitoring and supervising the urine output. Thus, we must provide an automatic mechanism to release the content of the sensor to a higher volume container, avoiding the need of healthcare staff to manually perform this operation several times each hour. Furthermore, the release of the content of the sensor must be performed exactly in the moment the container gets full, because once the container is filled the urine produced will not be registered until it is emptied. Therefore, the delays that might occur if the nursing staff had to manually release the urine -for example, because at the releasing time some emergency that requires the nursing staff attention has occurred in the critical care unit- would introduce errors in the measurements.

Several options were considered for an actuator for the urine release: a shaded pole motor, a stepper motor moving a screw, magnetism, etc. Finally, we opted for using linear solenoids because of their low cost, and because they are easy to control using a microcontroller. One solenoid is used for opening the valve, and a second one for closing it. However, adapting the design of the device proposed here to use any other actuator capable of opening and closing a valve to release the urine is trivial.

2.3 The microcontroller

The microcontroller we used in our prototype was an Atmel AT89S52, a 50 cents-a-unit, low-power, high-performance CMOS 8-bit microcontroller with 8K bytes of in-system

programmable Flash memory, 256 bytes of RAM, 32 I/O lines, two data pointers, three 16-bit timers, a full duplex serial port, on-chip oscillator, and clock circuitry.

As soon as the device is turned on, the microcontroller starts measuring the elapsed time. One of the three 16-bit timers is used for this purpose. The timer gets incremented once every instruction cycle. Since there are only two bytes devoted to the value of this timer, the maximum value it may have is 65,535. One instruction cycle in the AT89S52 has a duration of 1.085 microseconds. Three additional 8 bits registers are used to store the number of times that the timer overflows. The maximum time that can be measured is $((65535 \times 1.085 / 10E6) \times 255 \times 255 \times 255) / 3600$ hours, which is equal to 327.5 hours, close to two weeks. Thus, as long as the patient produces at least 15 ml of urine every two weeks, this timer will be enough.

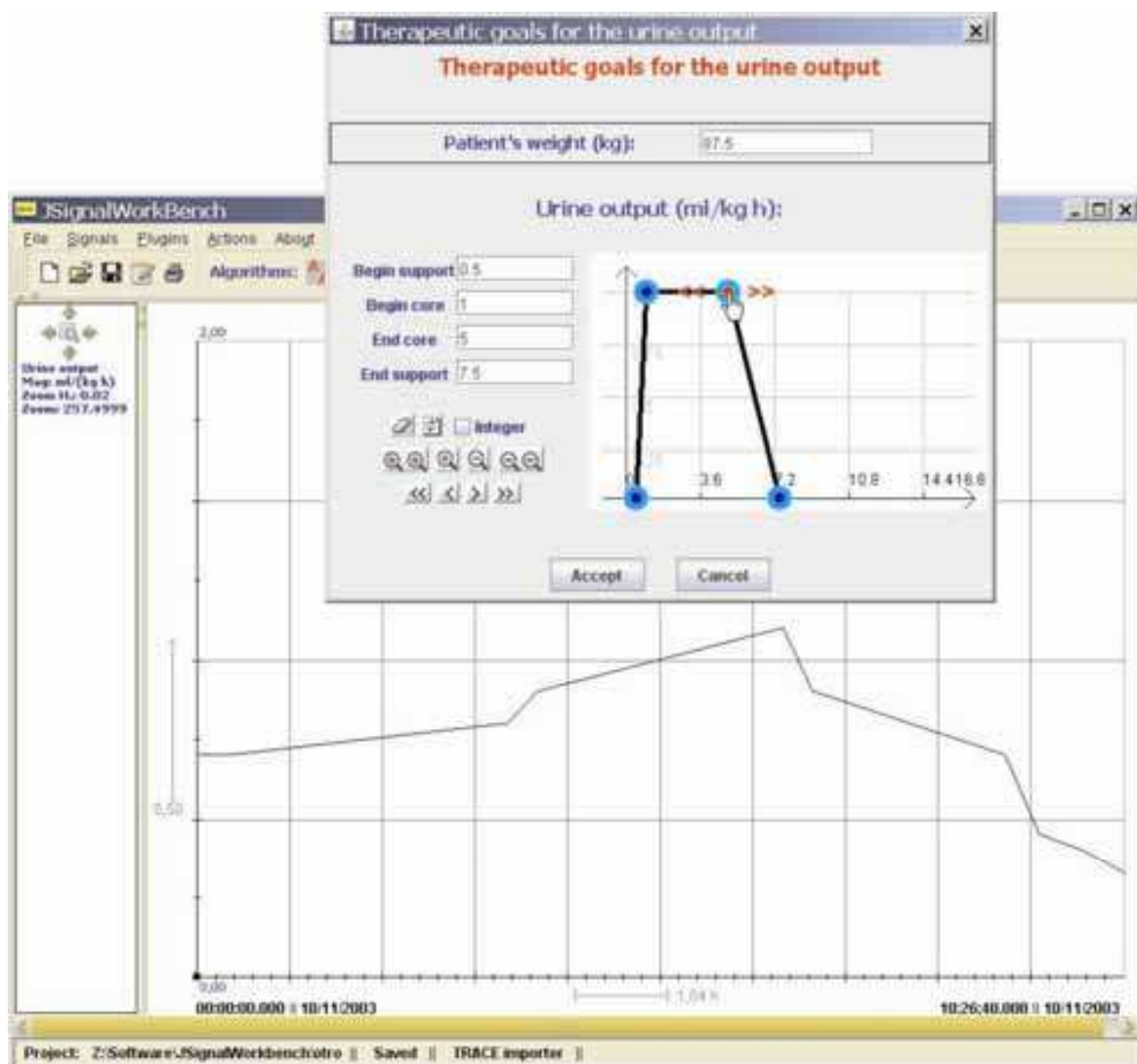


Fig. 5. Main screen of the Java application and the window that allows healthcare staff to set the therapeutic goals for urine output.

The physician sets the therapeutic goals for urine output on a computer using a program built for this purpose. From the therapeutic goals and the weight of the patient, this

program calculates the maximum time that should be required for filling the small container, if urine output is within the therapeutic goals, and the maximum time required for the large container. We shall call these times t_1 and t_2 , respectively. These times are sent to the microcontroller using the serial port. When the microcontroller receives this information, it replies sending back the time at which the monitoring started. This permits the synchronization of the microcontroller and the program installed on the PC.

Then, the microcontroller waits for the signal that indicates that the small container is full. If this signal arrives before t_1 seconds, therapeutic goals are being met and it is not necessary a very precise monitoring of urine output. Therefore, the valve shall not be opened, and the larger container starts to fill. If after t_1 seconds the signal indicating that the small container is full has not arrived, the microcontroller turns on an LED indicating that the therapeutic goals are not being met. In this case, a detailed monitoring of urine output is required. Thus, when the small container is full the actuator will be activated and the timer will be reset in order to measure, again, the filling time of the small container. If the small container has been filled within the expected time, but the large container is not filled before t_2 seconds, the alarm LED is also turned on. In either case, when the big container is full, the actuator will be activated.

Figure 4 shows a finite state machine detailing the operation of the microcontroller. The conditions that trigger the transitions are displayed as text on the arches that represent the possible transitions. t represents the time elapsed since the device was turned on, or since the last time the content of the sensor was released. Some transitions involve performing some action, such as firing an alarm or opening a valve. These actions are displayed as text drawn over the arches of the transitions and surrounded by a dotted line. All state transitions are communicated to the program installed in the PC via the serial port. This allows the PC program to calculate urine production at any given moment, and to find out whether the patient has anuria or oliguria.

In Figure 4, S_0 represents the initial state; S_1 corresponds to the filling of the small container before t_1 seconds; S_2 to the filling of the large container before t_2 seconds, S_3 to the non-filling of the small container before t_1 seconds; S_4 to the non-filling of the large container before t_2 seconds; and S_5 corresponds to the activation of the solenoid and the release of the urine. When the microcontroller reaches the S_5 state it immediately transitions to S_0 ; S_5 is a fictitious state which has been added to the diagram for sake of clarity.

2.4 Client software

We have developed a Java application that receives the readings of the urine output from the microcontroller through the RS232 port. To avoid the need for wiring, a serial-port-to-Bluetooth adapter has been used both in the PC and in the microcontroller. The program allows the healthcare staff to inspect a graph showing the patient's urine output in milliliters per hour (see Figure 5). It also has a screen showing a set of statistics, like the hourly and daily urine output throughout the stay of the patient in the critical care unit.

Using this program, the healthcare staff can set therapeutic goals for the urine output. These therapeutic goals are represented with the aid of the Fuzzy Set Theory, a tool which has proved its value for handling and representing experience-based heuristic knowledge, such as that commonly used in the medical domain (Barro & Marin, 2002).

We shall introduce some basic concepts of Fuzzy Set Theory on which our solution is based. Given as discourse universe \mathfrak{R} , we define the concept of fuzzy value C by means of a

possibility distribution π_C defined over \mathfrak{R} . Given a precise value $\nu \in \mathfrak{R}$, $\pi_C(\nu) \in [0,1]$ represents the possibility of C being precisely ν . A fuzzy number is a normal and convex fuzzy value. A fuzzy value C is normal if and only if $\exists \nu \in \mathfrak{R}, \pi_C(\nu) = 1$. C is said to be convex if and only if $\forall \nu, \nu', \nu'' \in \mathfrak{R}, \nu' \in [\nu, \nu''], \pi_C(\nu') \geq \min\{\pi_C(\nu), \pi_C(\nu'')\}$.

We obtain a fuzzy number C from a flexible constraint given by a possibility distribution π_C , which defines a mapping from \mathfrak{R} to the real interval $[0,1]$. A fuzzy constraint can be induced by an item of information such as "x has a low value", where "low value" will be represented by π_C . Given a precise number $\nu \in \mathfrak{R}$, $\pi_{C=\text{low}}(\nu) \in [0,1]$ represents the possibility of C being precisely ν ; i.e., the degree with which ν fulfills the constraint induced by "low value".

Normality and convexity properties are satisfied by representing π_C , for example, by means of a trapezoidal representation. In this way, $B = (\alpha, \beta, \gamma, \delta)$, $\alpha \leq \beta \leq \gamma \leq \delta$, where $[\beta, \gamma]$ represents the core, $\text{core}(\nu) = \{\nu \in \mathfrak{R}, \pi_C(\nu) = 1\}$, and $]\beta, \delta[$ represents the support, $\text{supp}(\nu) = \{\nu \in \mathfrak{R}, \pi_C(\nu) > 0\}$ (see Figure 5).

We shall represent the therapeutic goals for urine output by a trapezoidal possibility distribution. The minimum and maximum values acceptable for the urine output are the beginning and end of the support of the distribution, respectively. If urine output is lower (or higher) than this value the program produces an audible warning until it is turned off by the healthcare staff. The purpose of this warning is to identify oliguria and polyuria states. The beginning and end of the core of the trapezoidal possibility distribution are the limits of the interval within which ideal values of the urine output lay in.

The semantics of this possibility distribution is "adequate urine output"; therefore the degree of membership of a value of urine output to the possibility distribution indicates the adequacy of the patient's urine output regarding to the therapeutic goals. If the degree of membership is zero, either the urine output is less than the minimum acceptable value -the patient has oliguria or anuria-, or greater than the maximum acceptable -the patient has polyuria. If the degree is 1, the urine output is within the range of ideal values. The closer the degree is to 1, the closer the patient's urine output to the ideal value it is, and the closer the value to zero it is, the closer the patient is to oliguria or polyuria.

This information is represented by a color code that is used when drawing the graphs of urine output of the patient: a membership of 0 is associated with the color red; a value which lies in $]0, 0.2]$ is associated with purple; $]0.2, 0.4]$ with pink; $]0.4, 0.6]$ with orange; $]0.6, 0.8]$ with yellow; $]0.8, 1[$ with blue; and green with the total membership. In this way the graph of diuresis provides an instantaneous visual feedback on the patient state (Otero *et al.*; 2008).

Figure 5 shows the screen that permits the definition of the therapeutic goals. The trapezoidal possibility distribution that represents "adequate urine output" is obtained as the fuzzy product of the weight of the patient by the possibility distribution representing the number of $ml / (kg \cdot h)$ of urine output. This fuzzy product is defined as

$W \otimes (\alpha, \beta, \gamma, \delta) := (W \cdot \alpha, W \cdot \beta, W \cdot \gamma, W \cdot \delta)$ (Kaufmann & Gupta, 1984), where W is the patient's weight and $(\alpha, \beta, \gamma, \delta)$ represents therapeutic goals for the urine output.

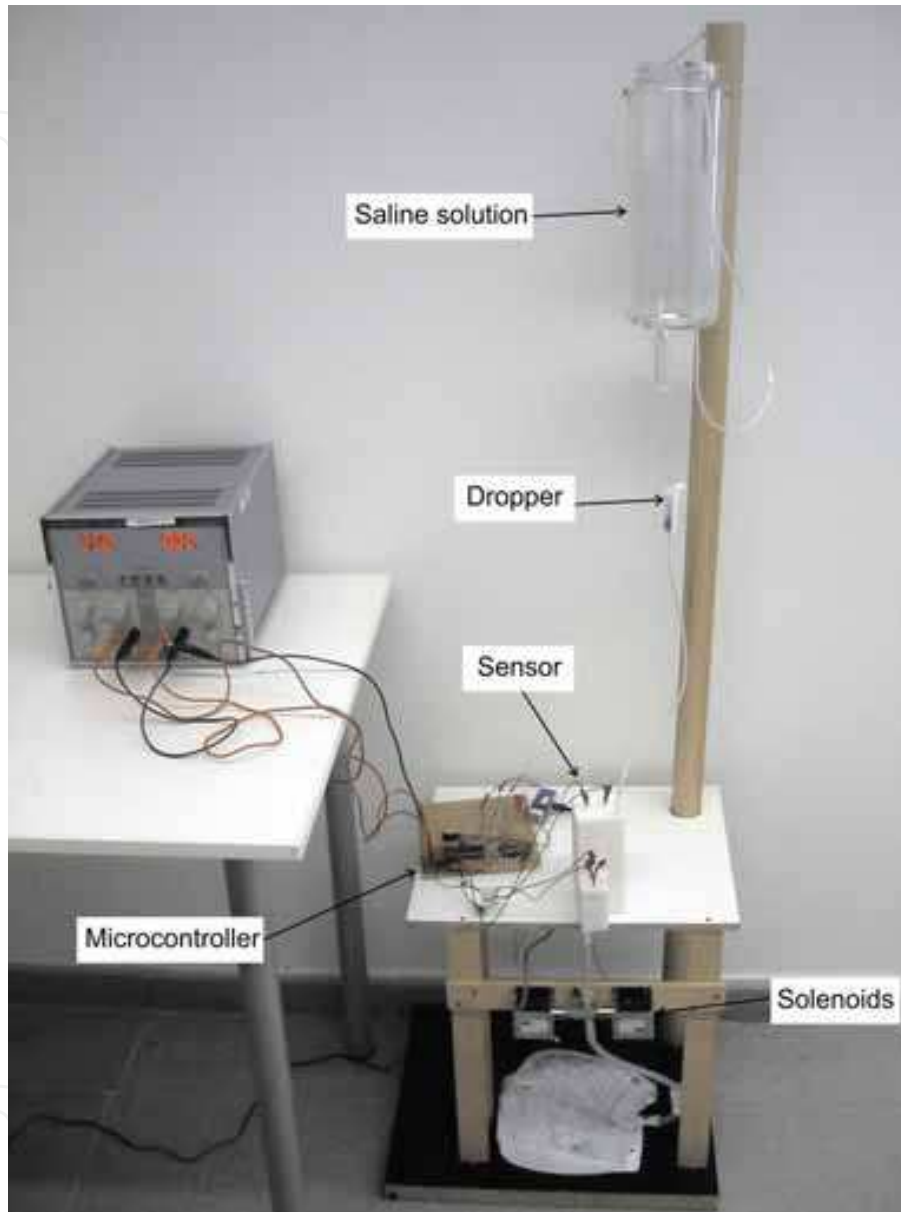


Fig. 6. Picture of the urine meter prototype.

3. Device validation

Once the device was built, a series of tests to verify its proper operation were performed. In the test a saline solution with similar properties to urine was used. This liquid was stored in a container placed at a higher level than the sensor, and a dropper was used to regulate the flow of fluid from this container to the sensor (see Figure 6).

The first tests failed for various minor mechanical problems. For example, the valve that releases the urine did not closed properly after the first opening, which produced a small dripping. Once this mechanical glitches were solved, a number of tests which forced the device to operate in all the states shown in the finite state machine of Figure 4 were performed. Several tests in which the amount of fluid sent to the sensor was carefully measured were also conducted, and then we verified that the production of urine provided by the software installed on the PC was accurate.

Finally, a stress test in which the system worked continuously for four days was conducted. After the four days, we check the state of all parts of the device, mainly the opening and closing valve –it still was able to completely seal the exit of liquid when it was closed; and the state of the floats and the metal contacts of the sensor –they showed mild corrosion that did not affect their operation. This suggests that the design of the sensor did effectively prevent the metal parts of the small container from being submerged in liquid.

4. Discussion

The tests we have performed show that our prototype device permits the automatic measuring of urine output with reliability and accuracy over a period of several days, and the generation of alarms when urine output deviates from the established therapeutic goals. To the best of our knowledge, no commercial or research device with these characteristics has been built until now.

Currently, in the critical care units, patients' urine output is registered manually by the nursing staff. Every hour a nurse must record the measurement of urine output from each of the patients in the unit, and must operate the valve that releases the urine from a graduated container to a larger container. This has to be repeated 24 times a day, 365 times a year. Every one or two days is also necessary to change the container where all the urine accumulates. We estimate that the amount of time required for the tasks associated with the manual monitoring of urine for every 10 patients admitted in a critical care unit is equivalent to the annual full-time dedication of a nurse. Therefore, total or partial automation of the tasks related to this activity can lead to considerable economic savings for the institutions that provide the care services.

The total cost of our prototype device was about 300 €. The most expensive parts were the serial-port-to-Bluetooth adapter, and the solenoids. We estimate that the cost of the disposable parts, if produced industrially, is less than 10 €; thus, the final cost of the device is comparable to the cost of the devices that are used to manually measure urine output. However, the workload that the device can potentially save, and therefore the savings in the cost of the health care service, is considerable.

On the other hand, all monotonous and repetitive tasks, as the one under consideration here, are prone to error. Therein lays the importance of automating them as much as possible. To provide a computer system to record and supervise continuously the urine output of all patients admitted to a critical care unit, and alert the healthcare staff on any deviation from the therapeutic goals, can potentially prevent human errors in this task.

Moreover, the monitoring interval currently employed in the urine output -one hour- tries to reach a compromise between avoiding risk states for the patient and not placing an excessive burden on the nursing staff. An automatic system, as the one described here, permits more frequent measurements to be carried out; thus it enables the identification of

deviations from normality at earlier stages. For example, the device described in this chapter, for a patient of about 80 kg, can generate a warning indicating oliguria in approximately 15 minutes.

5. Conclusion

We have built a device capable of automatic monitoring and supervising the urine output of critical care unit patients. The device is based on a sensor specially designed for this task. The sensor identifies the filling of two containers, one of 15 ml of capacity and another of 180 ml. A microcontroller processes the sensor output and, based on the filling time of the containers, it supervises if the therapeutic goals are being achieved. If the small container is filled on time, the patient is producing an acceptable amount of urine and it is not necessary a very precise monitoring of urine output; thus the microcontroller allows the larger volume container to start filling. If not, when the smaller container gets full, the microcontroller activates an actuator that releases its content. This enables a more accurate monitoring of urine output to be carried out, while limiting the stress suffered by the device's actuators. Whenever the big container is full, the actuator releases the content of both containers.

Therapeutic goals are established for each patient by the healthcare staff using a PC program. The program allows the healthcare staff to indicate the weight of the patient, the minimum and maximum acceptable values, and the ideal values for the urine output. The program also displays the patient urine output throughout his/her stay in the critical care unit, and alerts the healthcare staff of any deviation that occurs with respect to the acceptable values for the urine output. Using a colour code, it also indicates the deviation of the patient state from the ideal state.

The cost of non-disposable parts of the device is similar to the cost of current manual urinometers. However, this device can offset a considerable amount of workload from the nursing staff, translating in savings in the cost of the healthcare service rendered to the patient. This device can also help avoiding typical errors of monotonous and repetitive tasks, such as the one we have at hand, by automating the monitoring of therapeutic goals for the production of urine and warning when a deviation occurs.

Our future work is oriented towards the construction of a device similar to the one presented in this chapter, but sterilized, so it can be used in a pilot tests in the intensive care unit of the University Hospital of Getafe. A device of this type may also be the basis for carrying out a series of clinical studies based on a more continuous and accurate monitoring of urine output throughout the stay of a patient in the critical care unit.

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The field of biomedical engineering has expanded markedly in the past ten years. This growth is supported by advances in biological science, which have created new opportunities for development of tools for diagnosis and therapy for human disease. The discipline focuses both on development of new biomaterials, analytical methodologies and on the application of concepts drawn from engineering, computing, mathematics, chemical and physical sciences to advance biomedical knowledge while improving the effectiveness and delivery of clinical medicine. Biomedical engineering now encompasses a range of fields of specialization including bioinstrumentation, bioimaging, biomechanics, biomaterials, and biomolecular engineering. Biomedical engineering covers recent advances in the growing field of biomedical technology, instrumentation, and administration. Contributions focus on theoretical and practical problems associated with the development of medical technology; the introduction of new engineering methods into public health; hospitals and patient care; the improvement of diagnosis and therapy; and biomedical information storage and retrieval. The book is directed at engineering students in their final year of undergraduate studies or in their graduate studies. Most undergraduate students majoring in biomedical engineering are faced with a decision, early in their program of study, regarding the field in which they would like to specialize. Each chosen specialty has a specific set of course requirements and is supplemented by wise selection of elective and supporting coursework. Also, many young students of biomedical engineering use independent research projects as a source of inspiration and preparation but have difficulty identifying research areas that are right for them. Therefore, a second goal of this book is to link knowledge of basic science and engineering to fields of specialization and current research. The editor would like to thank the authors, who have committed so much effort to the publication of this work.

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