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System for the support of the intravenous infusion process continuity

Streszczenie. W pracy przedstawiono koncepcję systemu monitorowania spadku poziomu płynu infuzyjnego. Zadaniem tego systemu jest informowanie personelu medycznego o niskim poziomie płynu infuzyjnego w pojemniku. Ma to na celu umożliwienie wymiany (prawie) pustego pojemnika z płynem infuzyjnym na nowy, pełny pojemnik przed opróżnieniem komory kroplowej i drenu podłączonego do kaniuli dożylnej (wenflonu) na ciele pacjenta. W przypadku dostania się powietrza do drenu, wymiana go na właściwy płyn wymaga dodatkowych zabiegów. W praktyce klinicznej jest to często uciążliwe. Dlatego podstawowym zadaniem proponowanego systemu pomiarowego jest ostrzeganie przed całkowitym opróżnieniem układu infuzyjnego. Dzięki temu możliwa jest wymiana pojemnika z płynem sprawnie i bez dodatkowych komplikacji, utrzymując w zasadzie nieprzerwany proces dożylnego podawania płynu. (System wspomagający monitorowanie ciągłości procesu infuzji dożylnej)

Abstract. The work presents the concept of a system for monitoring the decrease in the level of infusion fluid. The task of this system is to inform the medical staff about the low level of infusion fluid in the container. This is to allow the (almost) empty infusion fluid container to be replaced with a new, full one before the drip chamber and drain connected to the venflon on the patient's body are emptied. In the latter case, replenishment of the fluid requires additional filling with a drip chamber and a drain. In clinical practice, this is often a nuisance. Therefore, the basic task of the proposed measuring system is to warn against complete emptying of the infusion system. Thanks to this, it is possible to replace the fluid administration.

Słowa kluczowe: leczenie, proces infuzji, system mikrokontrolerowy, pomiar masy. **Keywords**: medical treatment, infusion process, microcontroller system, mass measurement.

Introduction

In everyday anaesthesiological practice a physician and a nurse create a team that takes care and safety measures during surgery. Anaesthestic work requires constant attention focused on the administration of anesthesia, observation of the operating field and the patient's vital signs, and the appropriate response to events that occur in the dynamic process of the surgery. The senses that are most involved in the anaesthetic work are sight, hearing and touch. Visual and sound signals from a cardiac monitor, anesthesia machine and surgical devices, verbal communication with the surgeon, blood vessel cannulation, the whole range of regional anesthesia procedures, parenteral administration of drugs - these are just a few of the areas that remain at the anaesthesiologist's disposal and contribute to the effective management of the patient through a stressful situation of surgery. Thus, properly set visual and audible alarms are the elements that significantly improve patient safety, notifying the anaesthesiological staff about the situation beyond the set norms.

Patient condition monitoring during anesthesia includes, among other measurements of the blood pressure, heart rate, ECG, saturation, the level of exhaled carbon dioxide, concentrations of medical gases and inhaled anesthetic, pressures in the respiratory tract, the degree of muscle relaxation. Each of the parameters requires the attention of a physician or a nurse. The emerging alarm focuses their attention on the parameter, a deviation may turn out to be critical at the given moment. The anesthetic team is particularly sensitive to the sound signal from the measurement of saturation. Its rhythm and pitch, which constantly accompanies the anaesthesia, are one of the most important information about the patient for the anaesthesiologist.

During the preop-meeting, the anaesthesiologist asks the patient about their diseases, medicines, and the patient's medical history. They are interested in patient's laboratory and imaging studies. They have to know about all the potential patient's abnormalities. Although the anaesthesia affects almost all human body organs, it is mainly realized by influencing respiratory and cardiovascular systems. Each patient must have an intravenous cannula. Through a cannula, the anaesthesiologist administers drugs, medical fluids and, if

necessary, blood products. Intravenous cannula insertion is a basic element of patient safety. It enables the immediate administration of drugs or fluids, and allows them to work immediately.

Apart from intravenous drugs, special fluids are administered during anesthesia. These are electrolyte solutions, hydroxyethyl starches or gelatins. These fluids are administered as a supplement to the lost fluids during surgery. During anesthesia, the anesthetist gives many different drugs and fluids in 50 to 1000 milliliter containers, which must be changed quite often. They use an IV kit consisting of:

- a drain with a drip chamber, i.e. a several centimeter long widening in the form of a cylinder,

- a movable clamp on the drain,

- end 1 - hammered into a container with a liquid, in the form of a pointed tube,

- end 2 - end of the drain with a thread, screwed on a cannula.

The container with the liquid is always placed about 1-1.5 meters above the lying patient. This allows gravity to flow into the venous system, where the pressure is lower than that exerted by the liquid column in the reservoir and drain. The fluid flows down until the pressure is equal with the patient's venous pressure. During the complete drainage of the fluid from the container through the tubing into the cannula and the patient's venous system, fluid usually stops in the drain. Starting the next fluid bottle outflow would cause air to enter the patient's venous system. It may create a very dangerous complication called "venous air embolism" (VAE), which could lead to arrhythmias and cardiac arrest. For this reason, it is required to remove the rest air from the drain. Then a drain requires filling with the new fluid and then starting the drip infusion.

There are several possibilities for the staff to empty the drain from the air. Some of them require action and it is possible to contact blood or dirty the set. Using a clamp on the drain, the personnel prevents the drain from emptying completely and then connects another fluid bottle. It is possible when the proper moment is noticed by the anaesthesia team. However, in everyday practice, among many other activities the moment is sometimes missed. Especially during anesthesia that requires extraordinary activities from the physician and the nurse, which engage their special attention.

There are infusion pumps and drop counting devices used for regulated administration of intravenous drugs during surgery. However, fluid therapy on an operation theater requires a constant attentiveness of the staff. This emerges a need of an alerting device that alarms the ending of fluid in the container.

The hook scale (system for the support of the intravenous infusion process continuity) with an alarm accommodates the need. The scale is hung on the operation stand. The fluid container is attached to the scale.

The user sets on the scale the desired weight of the fluid bottle associated with an alarm. Then, the infusion can be started. When the bottle weight decreases to the set level, the scale alarm beeps. The user has some time to stop the fluid using the clamp on the drain. The scale does not cause any other problems. It does not interfere with the infusion, it has no contact with the patient, it is completely safe. In the case of the device failure or unnoticed alarm, anaesthesiological procedures remain the same as previously.

As explained above the design of a device to monitor the process of intravenous administration of drugs is dictated by the need to maintain the continuity of this process. During medical procedures or intensive care, there is a need for long-term and at the same time continuous administration of intravenous drugs. At this point, the long-term nature means the need to replenish the infusion fluid. The gravity fluid feeding system consists of a fluid container, a drain with a drip chamber (Fig. 1) and ends with a venflon attached to the patient's vein.



Fig 1. Sample of the fluid container and drain with a drip chamber.

In medical practice, it is important that the fluid container is replaced at the right time before it is completely emptied. Then the task basically boils down to substituting the fluid container itself. Otherwise, the fluid will leave the tray, then the drip chamber and the next part of the drain where it will stop in a certain part of it, in which, according to the laws of physics, the pressures will became balanced. Unfortunately, this happens every day in clinical practice. Thanks to the scale with alarm function and fluid retention while still in the drip chamber, one does not need to replace the drain or push the fluid up into the drip chamber. One can connect another fluid container immediately after the previous one, without a combination with an empty drain. The problem is described in the literature [1,2,3] as there is a significant need to monitor the process. There are different ways to achieve this including reflection (infrared or ultrasonic detectors) and impedance measurement. The paper presents another possibility based on the mass measurement . The aim of the work is to propose simple, reliable and of course not too expensive method supporting medical treatment.

Measurement System

The proposed system shall take the form of an electronic scale which continuously measures the mass of the infusion

system and generates alarm information (sound) when its mass reaches a certain minimum level associated with the emptying of the liquid container. The scale was made as a battery-powered microcontroller system, with a strain gauge and a warning sound source. At the heart of the measuring and control system there is the Arduino UNO board with AVR ATmega 328 microcontroller [4,5], extended with a standard display with keyboard for device control and menu operation [6]. A tensometric beam of a range covering the available capacities of infusion fluid storage units/bottles (100 to 2000ml) was used to measure the mass [7]. A typical buzzer was used as a sound source at the initial stage of research (Fig. 2).



Fig. 2. Electronic components of the scale (from the top: Arduino								
UNO	board,	LCD	Keypad	Shield,	strain	gauge	with	signal
conditioning and tensometric beam; buzzer in the left lower corner).								

The microcontroller can be programmed in the Arduino IDE, native programming environment or in general AVR microcontroller programming environment like Microchip Studio. Both software environments were involved while programming the device.`

Components used for the scale are commonly available in the market. They meet the measurement device requirements including additional demand for the measurement system to be cheap. The latter property fulfils application and economic anticipation. On the other hand these components are of the general and universal use. That is why the initial overall size of device composed of these elements does not have to be optimal. In turn contemporarily available elements are ready to use (conditioned, soldered on the PCB and equipped with standard connectors) or require few steps to adapt them for mount into the device. This all makes possible the initial design to be very short (a week in the presented scale case) Of course the design from the scratch of the scale will also help in optimising the device parameters including its dimensions.

Further work also allows for sophisticated user interface most interesting alarm indicator. It can be formed in a block of LED ruler indicating fluid level and alarm stage. It is also possible to install commonly available music/mp3 player module with sound information. This is being considered as there are many patient's condition monitoring devices generating self-specific sounds. Thus a new proposed device should not be a source of sound specific (or even proper) to other (standard) monitoring devices. Independently the future versions of the device need to be equipped with the battery level control module. Current work is focused on development of the process demonstrator which can be charged by some disadvantages at the present stage. Most or even all of them can be minimised or completely removed during improvement work. The fundamental aim of the research is to confirm the possibility, the need and the legitimacy of functional device development. The device that can serve as a base for the application of the anticipation and ideas proposed by the medical personnel.

Functionality

The device is designed to monitor the level of infusion fluids by measuring the mass of typical infusion fluid containers in the range of 100 to 2000 ml. By empirical means, net mass, gross and tare values were determined. The alarm level can be set in the range of 5-20% of the initial net mass of the fluid, depending on the type of packaging. Each time one turns on the device (fig 3.), it can be calibrated.

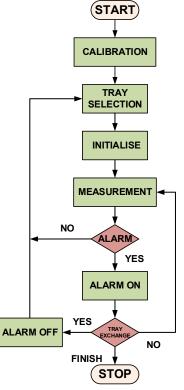


Fig 3. Basic diagram of the scale algorithm.

Next, selection the size of the container is to be completed, after which one can start the process for monitoring the level of the infusion fluid. The process is being continued until the level of the fluid becomes alarmingly low.

At present when the alarm level is reached, a beep sound is activated. There are two characters of sound: interrupted and continuous splitting the indication into alert and alarm steps. This action reminds the personnel to replace the container, effectively. As it is completed, one sets the capacity of the new container and the monitoring procedure can be started again. The developed concept of the measurement device is presented in the fig. 4.

Measurement System Evaluation

The aim of the project was to create a device that will allow to notice the moment just before the drip chamber is completely empty. The "scale with alarm" prototype was subjected to clinical trials. The scale was suspended on a stand with a rubber band. The drip tube was connected to a cannula in the patient's peripheral vein. Then, in some cases, the tube was attached to the patient's skin at a distance of approx. 20 cm from the cannula for protection from additional forces. The scale was handled as instructed after each additional bottle of liquid was suspended. The fluid container was observed during the infusion and the fluid flow rate was controlled as clinically needed.

The alarm was triggered at the expected moment after reaching the mass set point. It was observed that in each case fluid was still present in the container as expected. The alarm signal let control the flow of the fluid in such a way that it does not leave the drip chamber. This control took about 1-3 minutes. When an alarm occurs, the user should have no more than about 10 seconds to react. Filling the drip chamber is a key element to achieve the aim.



Fig. 4. The developed concept of the infusion fluid level monitoring system.

Initial intermittent beep (warning 1) is changes into continuous beep (warning 2) after several seconds. The sound of the scale alarm was a new one for the staff as intended not to be mistaken with other, standard ones. The device has been pre-calibrated for 100, 250, 500 and 1000 ml liquid containers.

Preceding the initiation, the evaluation procedure in a medical diagnostic field the device was tested against its reliability. Its functionality covers the calibration routine that can be carried out prior each usage or the "factory" settings can be used instead. As the scale is to be used for the intravenous fluid containers of the most popular sizes ranging from 100 ml (g), including 250, 500 and finally ending with 1000 ml (g) size. In order to verify the overall usefulness and reliability of the devices it was verified as a scale with laboratory, precision weights in series given by 10, 20, 30, 40, 50, 60, 70, 80 and 90 g and respectively 100, 200, 300, 400, 500, 600, 700, 800, 900 and 1000 g. Measurements were repeated several times for the complete set of weights. The maximum measurement error did not exceed 2% for all cases, did not change enormously for different weights and has got "a constant sign" measured value was smaller than the weight used. This is fully satisfying value especially for the reason that the device is characterised by the threshold operation for which the internal measurement errors can be easily compensated.

Finally relevant settings were added and are available in the menu. It is reasonable to supplement the functionality of the device with the possibility of adding other fluid containers by the end user. During drip infusion empirical observation described by the laws of physics is used. In order to accelerate the intravenous infusion, the IV stand (IntraVenous stand) with fluid container is mechanically raised. Due to the size (height) of the device bottle and the suspension (approx. 50 cm in total), sometimes it was not possible to increase the height of the liquid bottle to the desired height. Thus, one of the further challenges is to construct a device with possibly reduced dimensions.

The device was pre-tested in an operating room. The description above reflects the facts and expectations regarding the designed device in these circumstances. Finally, it is worth noting that adding a wireless module (Bluetooth, WIFI) to a device can help nurses work in hospital wards. The alarm in the smartphone or even SCADA class application would allow better control of intravenous infusions at patients' beds.



Fig. 5. Daily activities in medical procedures test.

Adding a communication module (wired serial interface, Ethernet or wireless like Bluetooth, Wi-Fi) onto the device can help the personnel work in hospital wards. With a use of the communication, it is possible to develop distributed measurement system and monitor many infusion procedures being performed in the hospital ward from a single place - personnel on duty console display. It would also be possible to develop a smartphone application for the control of intravenous infusions at patients' beds. Authors also keep in mind that the mass measurement method is sensitive to any movement, so the system is to be handled steady. The tests performed in the hospital conditions pointed the sensitivity of this aspect and it is planned to involve other mentioned methods to be used even in parallel if needed.

Summary

The scale design is a response to the idea presented by physicians and is due to the problems encountered during daily activities in medical procedures (figure 5). The monitoring system has undergone an initial phase of engineering testing resulted in satisfactory outcomes. The phase was followed by the attempt to clinician tests. Though they revealed some weaknesses concerning the dimensions of the scale prototype, duration and sound properties of the alarms, time aspects of the generated alarms and finally the need of the more complex scale operation menu (alarm postponement and clearing, different possibilities of the fluid containers interchange support, etc.) in general the clinician tests ended up with positive outcomes at the presented stage of scale development. So it is reasonable to apply necessary modifications making the device fulfilling the demands of the qualified personnel. Some of them like the need of size reduction can be achieved by reconstructing the device and splitting it into two modules: the tensometric beam/hook module and display module. The previous one can be mounted on the top of a IV stand while the latter one at the height of eves also on the stand. Both modules can be connected by a spring cable.

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