

Pain Management System with Intermittent Boluses and Monitoring of Bio-signals

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Abstract—The objective is to design a microcontroller based pain management system which reduces the pain of the patients by giving analgesics epidurally, monitors the given parameters and activates alarms in case it identifies any deviation along with the type of alarm on the display. The epidural infusion involves injection of drugs through a catheter placed into the epidural space. This system allows the user to enter analgesia rate, time duration between two boluses, bolus volume and drug name through keypad. Although it provides continuous and intermittent type of infusion, intermittent bolus method is more effective than continuous infusion method. The basic requirement is to infuse analgesic drug of a selectable dosage in ml, after a fixed time gap in minutes and at a programmed analgesia rate of (say) 299 ml/ hr entered by the user, till the system is reset or an alarm condition gets activated. The mechanical assembly consists of peristaltic mechanism which is driven by a stepper motor. It gives information about infusion rate, drug name, elapsed time and infused volume at a glance to the doctors or nurses. It also has continuous monitoring of bio-signals like electrocardiogram and photoplethysmography signal. The bio-signal monitoring helps doctors to decide change in analgesia rate. These are the vital parameters that need to be monitored for personal healthcare. This system has applications in many fields of medicine like painless labour in obstetrics, oncology and orthopedics.

Keywords—epidural infusion, catheter, analgesia rate, intermittent bolus method, peristaltic mechanism, painless labour, continuous and intermittent type of infusion.

I. Introduction

Nowadays there are number of medical procedures which require a prolonged period of intravenous infusion. Intravenous infusion is inserting a fluid or medicine into the patients' veins. It can be intermittent or continuous. Continuous administration of infusion is called as an intravenous drip. The word intravenous simply means "within a vein", but is most commonly used to refer to IV therapy. The pain management system is based on IV therapy. It reduces the pain of the patients by giving analgesics epidurally, monitors the given parameters and activates alarms in case it identifies any deviation along with the type of alarm on the display. The term epidural is often used for epidural anesthesia, a form of regional anesthesia involving injection of drugs through a catheter placed into the epidural space. The injection can cause both a loss of sensation (anaesthesia) and a loss of pain (analgesia), by blocking the transmission of

signals through nerves in or near the spinal cord. The epidural space is the space inside the bony spinal canal but outside the membrane called the dura mater.

The simplest form of intravenous access is a syringe with an attached hollow needle. The needle is inserted through the skin into a vein and the contents of the syringe are injected through the needle into the bloodstream. The most commonly used device for the intravenous infusion is a hand operated or hand delivered IV set with a plastic roller to adjust the infusion rate manually. The disadvantage of this method is that it requires a nurse or other health-care professional to adjust the infusion rate with the help of a roller.

II. Methods

The infusion rate in IV set based manual method is gravity dependent. As the height of liquid column in saline bottle decreases, the pressure exerted by the liquid decreases as per the formula: $P = \rho * g * h$

As a result, the infusion provided is not precise and delivery of drug becomes irregular. It is undesired effect in case of critical patients in the ICU. To overcome the disadvantages of IV set based method and to achieve precise and regular infusion of drugs, infusion pumps are designed. The infusion pumps are widely used in cardiac ICU, neonatal ICU and operation theatre in hospitals. There are two types of infusion pump:

A. Peristaltic Infusion Pump:

Peristaltic infusion pump is generally the micro-processor or microcontroller based device used for precise and uniform infusion of fluids. It is dedicated to intravenous dosage of little volume medicaments such as antibiotics, anesthetics, analgesics and chemotherapy reagents with very high accuracy. It is used for all types of intra-arterial and intravenous infusions requiring accurate administration of IV fluids and critical drugs such as Bupivacaine, Fentanyl and Lignocaine etc. Peristalsis is the sine wave shaped motion of plastic plates placed along the tube containing liquid inside infusion pumps. Further it can be made to merge on-line measurements such as systolic arterial pressure and heart rate and non-numerical clinical signs (such as sweating, lacrimation and pupil response) using anaesthetists' experience or self-organizing fuzzy logic control algorithms to administer drugs into a patient [1].

Intermittent infusion has a "high" infusion rate, alternating with a low programmable infusion rate to keep the cannula open. The timings are programmable. This mode is often used to administer antibiotics or other drugs that can irritate a blood vessel.

B. Syringe Pump:

The micro-controller based device used for precise and accurate infusion of any kind of liquid is called as syringe pump. Syringe pumps are used for infusion of fluid volumes less than 60 ml. Syringe acts as a liquid reservoir in syringe pumps.

Pain Management:

Pain management (algiatry) is a branch of medicine employing an interdisciplinary approach for easing the suffering and improving the quality of life of those living with pain. The pain scale consisting of 7 faces is sometimes used to take feedback from the patients [2]. Currently the doctors provide boluses manually using a syringe. They insert a catheter into the epidural space of the patient using a needle. Figure 1 shows insertion of catheter in epidural space using a needle.

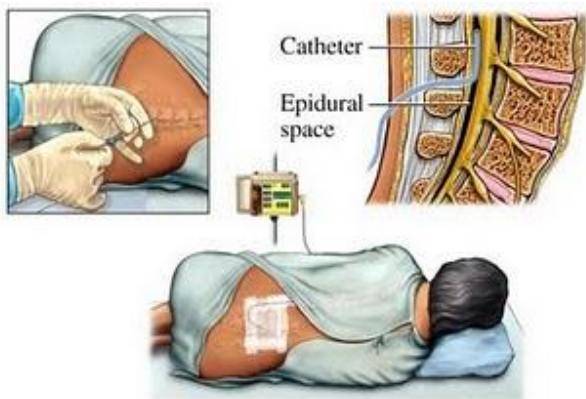


Figure 1: Insertion of Catheter in Epidural Space

Types of Infusion:

- A. Continuous infusion at constant rate
- B. Programmed intermittent boluses
- C. Patient controlled analgesia

The continuous infusion method is widely used but programmed intermittent boluses technique is more effective over the first method. In the first method, drug is infused at a specific rate continuously. The drop mode and volumetric mode are modes of continuous method. In the intermittent bolus method, boluses are provided after a specific time delays. In patient controlled analgesia, a doctor will configure this mode and a patient will be able to add an extra shot of drug if drug lock-out logic permits. Prospective randomized study was designed to compare the safety and efficacy of administering small, frequent boluses of Bupivacaine and Fentanyl mixture epidurally for labor analgesia maintenance, with that of continuous infusion and traditional intermittent boluses. The study revealed that the technique of small

frequent boluses at fifteen min intervals is superior to the technique of traditional intermittent top-ups but not to the technique of continuous epidural infusion as regards quality of analgesia. The doctor will be able to add an extra shot of analgesia or reduce a preprogrammed analgesia shot as per requirement by simply pressing a switch. This mode will be switched on by the doctor during configuration with lockouts. The Table 1 shows the basic parameters that have to be entered by operator according to selected mode.

Drop Mode	Volumetric Mode	Pain Management Mode
IV Type	IV Type	IV Type
-	Volume Limit	Bolus Volume
-	-	Time duration between two boluses
Time Limit	Time Limit	-
Infusion Rate (Drops/min)	Infusion Rate (ml/hr)	Analgesia rate (ml/hr)
Drug Name	Drug Name	Drug Name

Table 1: Modes of Pain Management System

iii. System Details

Features of the System:

- 1. Bolus Volume selection
- 2. Time Duration selection
- 3. Analgesia Rate selection
- 4. Alarms
- 5. Drug library
- 6. Peristaltic mechanism with stepper motor
- 7. Battery back-up
- 8. Real time clock

System Block Diagram:

8* 3 matrix keypad is used as an input device. It is used to enter parameters such as mode of operation of system, IV type, analgesia rate, bolus volume and time duration. The opto-coupler circuit consists of an IR LED 55C and photodiode L14G3 pair. They are mounted around the drip chamber to sense the drops that emerge from the reservoir. As per the set rate, micro-controller calculates the speed of stepper motor and time gap to fall one drop and drives stepper motor on calculated speed. The stepper motor shaft is linked to peristaltic mechanism to infuse drug into the patient's body. High precision infusion rate is available due to micro-controller based design. 20*4 LCD is used for displaying various parameters and alarm conditions to the operator. When alarms conditions are reached, audio visual alarms also get activated. The AT89S8253 is a low-power, high-performance

CMOS 8-bit microcontroller with 12K bytes of In-System Programmable (ISP) Flash program memory and 2K bytes of EEPROM data memory. The block diagram of the system is shown in figure 2.

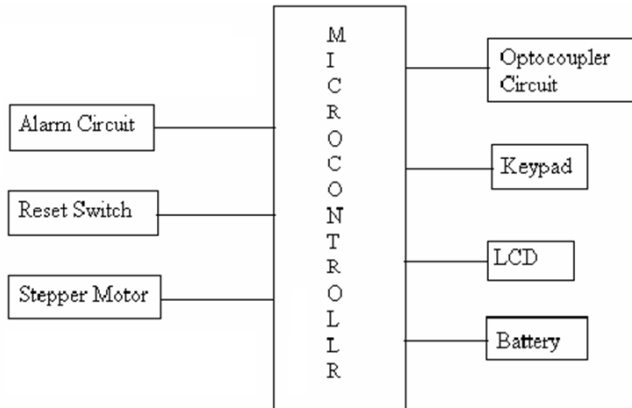


Figure 2: Block Diagram of the System

The pump should be able to infuse analgesic of a selectable dosage in ml, after a fixed time gap in minutes & at a pre-decided infusion rate of (say) 299 ml/ hr, till the pump is reset or an alarm condition gets activated. Once the infusion is on, the pump should display the Infusion Rate, Time Elapsed since start of Infusion & Total Volume infused and then show the mode selected on the display ‘Pain Management’.

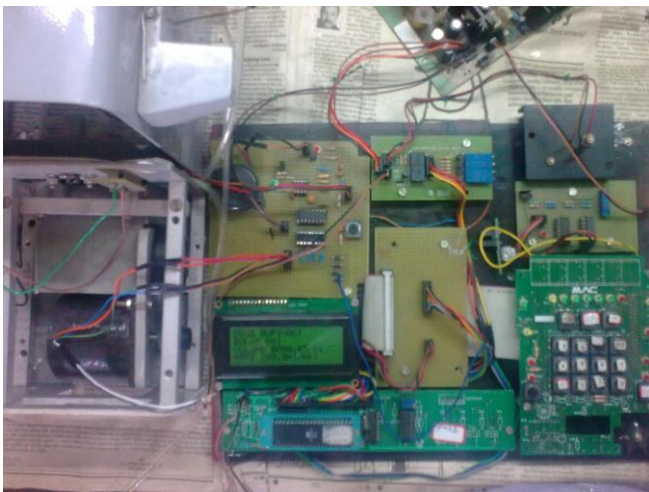


Figure 3: System Setup

The pump logic should monitor the given infusion’s precision and activate alarms in case it identifies any deviation along with the type of alarm on the display. The system setup is shown in figure 3.

Mechanical Assembly:

The mechanical assembly consists of a row of cam-operated fingers that compresses the tube in wave-like motion, squeezing the liquid as wave progresses. It is known as peristaltic mechanism which is driven by a stepper motor. A rotor with external circumference compresses the flexible

tube. As the rotor turns, the part of tube under compression closes thus forcing the fluid to be pumped to move through the tube. The advantage of this mechanism is that the fluid does not come in direct contact with pump, avoiding contamination. The mechanical assembly is shown in figure 4.



Figure 4: Mechanical Assembly

Checking for Alarm Conditions:

Audio-visual alarm circuit consists of a buzzer and an LED. Transistor BC 547 is used as a switch. When a high level voltage or +5V is applied at the base of transistor, it acts as a short circuit. So buzzer rings and LED turns on. When ground is connected to the base of transistor, it acts as an open circuit and buzzer and LED turn off.

A. Invalid Rate:

When rate is selected by user compare it with zero and ring buzzer if the selected rate is zero drops/ min.

B. High Flow Rate:

After starting infusion, store number of drops infused in a minute continuously. After end of the minute restart the counter for drops. Compare the number of drops infused with the set rate. If the difference between them is greater than +/- (10 % set rate +5), then ring buzzer.

C. Low Flow Rate:

Compare the number of drops infused in the minute with the set rate. If the difference between them is greater than +/- (10 % set rate +5), then ring buzzer.

D. Air in Line Detection:

Optocoupler H22A1 is used to detect presence of air bubble. H22A1 consists of an LED as a transmitter and a phototransistor as a receiver. Current limiting resistors are connected to input of optical sensor. The OP-AMP acts as a voltage comparator [5]. The output of optocoupler is given to input pins of OP-AMPS in IC LM 339. It compares the voltages with reference voltage 1.5V to get difference between output voltage levels. It provides high to low pulse to microcontroller when there is an air bubble inside the tube [4]. The same logic is used for detection of fall of a drop in drop chamber. The figure 5 shows air in line detection circuit.

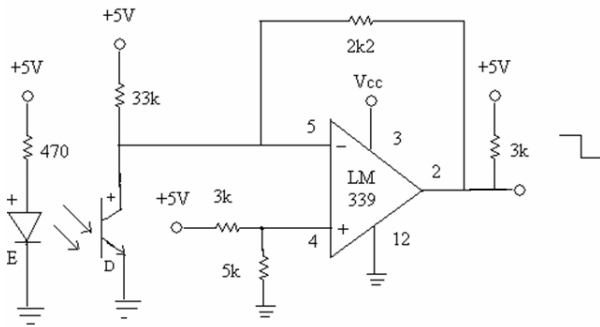


Figure 5: Air in Line Detection Circuit

Electrocardiogram:

Electrical activity associated with function of the heart is known as electrocardiogram. The horizontal segment of this waveform is designated as baseline or iso-potential line. P wave in ECG represents depolarization of atria. The QRS complex is the combined result of repolarization of atria and depolarization of ventricles which occurs almost simultaneously. T wave represents ventricular repolarization and U wave is believed to be the result of after potentials in ventricular muscles. PQ interval represents delay in excitation wave generated from SA node. This wave is delayed in fibers near AV node.

ECG Signal Conditioning Circuit:

Buffer is an impedance matching circuit used to avoid loading effect [5]. Each lead should have a buffer to avoid effect of half cell potential of electrodes. The non-inverting amplifier has high input impedance to avoid polarization effect in electrodes. The instrumentation amplifier is there to get high gain and high CMRR to reject some common mode signals present like motion artifacts, drying of gel and muscle tremor etc. This is a right leg driven circuit as it increases CMRR and system performance. The frequency response of ECG signal is about 0.05 to 100 Hz. Therefore there is a need of a band pass filter which is made by cascading a low pass filter and a high pass filter. These filters are passive filters made up of resistors and capacitors.

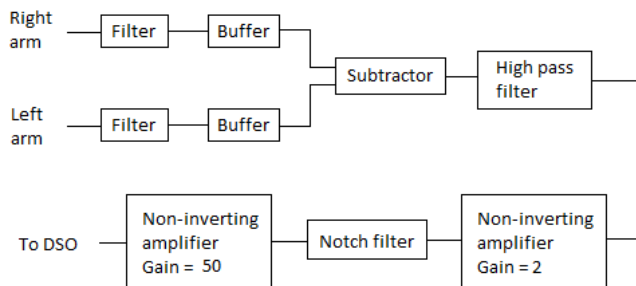


Figure 6: ECG Signal Conditioning Circuit

A notch filter is used to remove 50 Hz power line frequency noise. It is basically a twin-T network in which one T network is made up of two resistors and a capacitor while the other uses two capacitors and a resistor. The obtained

signal is observed on Digital Storage Oscilloscope. The signal conditioning circuit for ECG is shown in figure 6. The heart rate is displayed on LCD after completion of a minute as the output of voltage comparator is connected to external interrupt pin of microcontroller.

Photoplethysmography:

Photoplethysmography is an instrument used mainly to determine and register the variation in blood volume or blood flow in the body with each heart beat. PPG is basically a process of applying a light source and photo-sensor to an appendage such as a finger or a toe and measuring the light reflected by the skin. A light source in an opaque chamber illuminates small area of fingertip. The photo-transducer picks up light scattered and transmitted through the capillaries get filled with blood with each pulse, the blood density increases thereby reducing the amount of light reaching the photo-transducer. In this method, there is a rice lamp used as a photo-source and LDR as a photo-detector.

Systolic blood pressure is estimated from Pulse Transit Time. PTT is the time taken for arterial pulse pressure wave to travel from aortic valve to a peripheral site. It is usually measured from the R wave on ECG to a PPG signal. PTT is inversely proportional to BP. PTT is typically about 250 ms. The non-invasive, cuffless and continuous measurement of BP can be done by ECG and PPG.

PPG Signal Conditioning Circuit:

The acquired signal consists of AC as well as DC components. The DC component is because of non-pulsetile arterial pressure, venous blood, skin color, bones and tissues, while the AC part is because of pulsetile arterial blood. The DC component is a variable value. To remove this unwanted DC offset, a subtractor stage and AC coupling is used [5]. The arterial pulse wave is produced by low amplitude mechanical vibrations. Thus, change in reflected light is also small resulting in weak signal. Hence the amplifier stage is added to the system. The LDR is connected in voltage divider network, the output of which is around 3 V DC. Adjust the reflection voltage of subtractor such that this DC offset is minimized. The next is non-inverting amplifier whose gain is adjusted to 11. A non-polar capacitor of 1µF is used for AC coupling. Another amplifier stage is added to provide sufficient gain. The signal conditioning circuit for PPG is shown in figure 7.

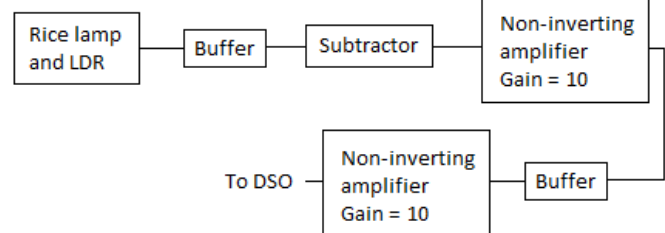


Figure 7: PPG Signal Conditioning Circuit

Probe design:

Use a square-shaped box as an enclosure. Solder the photo-source and photo-detector on a small piece of PCB. Use

shielded cable for supply of photo-source and LDR's output connection. Make holes on box of the size same as that of LDR and rice lamp. Fit the PCB in the box and pack it by using a sponge. Attach a Velcro strip to PPG enclosure. Wrap Velcro strip around the finger to minimize motion artifacts. The design of PPG probe is shown in figure 8. Figure 9 shows PPG and ECG signals observed on DSO.

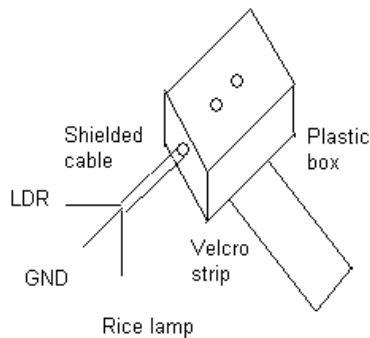


Figure 8: PPG Probe

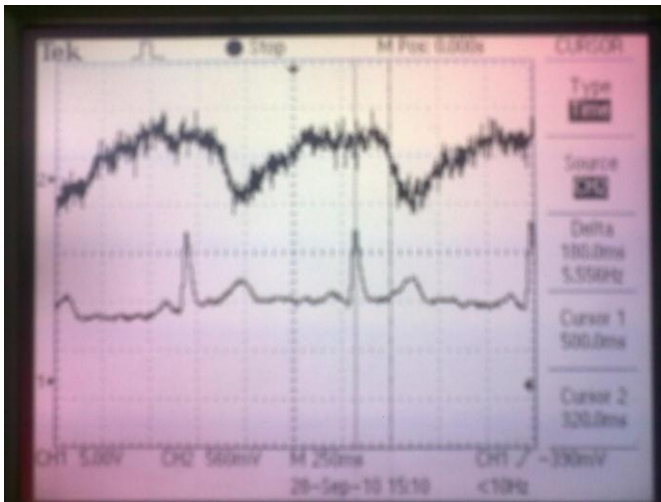


Figure 9: PPG and ECG signals observed on DSO

iv. Conclusion

The pain management system is a micro-controller based device used for uniform and accurate infusion of any kind of fluids. It has three modes of operations viz. Drop, Volumetric and Intermittent Bolus mode and these three

modes make the pump extremely versatile. Microcontroller provides calculated infusion rate and delay between two steps of stepper motor sequence. When an abnormal condition occurs, alarm rings for no infusion rate, infusion rate beyond range, air in line etc. Real time clock provides elapsed time and time remaining for the next bolus. The monitoring of bio-signals like ECG and PPG helps doctors to decide change in analgesia rate. The main advantage of this pump is that, it is an attempt to automate the manual process of infusing analgesic solutions in the hospitals and also reduces the monitoring time of nurse and manual errors.

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